IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE:	)	
	)	CA No. 01-12257-PBS
PHARMACEUTICAL INDUSTRY AVERAGE	)	CA No. 06-11337-PBS
WHOLESALE PRICE LITIGATION	)	Pages 1 - 111
	)	

MOTION HEARING

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
October 20, 2009, 2:10 p.m.

LEE A. MARZILLI
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United States District Court
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P R O C E E D I N G S

THE CLERK: In Re: Pharmaceutical Industry Average Wholesale Price Litigation, Civil Action 01-12257 and 06-11337, will now be heard before this Court. Will counsel please identify themselves for the record.

MR. HENDERSON: For the plaintiffs, United States of America, George Henderson, AUSA.

MR. FAUCI: James Fauci with the United States Attorney's Office.

MS. ST. PETER-GRIFFITH: Ann St. Peter-Griffith from the United States Attorney's office, Southern District of Florida.

MR. LAVINE: Mark Lavine with the U.S. Attorney's office, Southern District of Florida.

MS. OBEREMBT: Laurie Oberembt. I'm with the Civil Division.

MR. BREEN: Jim Breen for the relator, Ven-A-Care of the Florida Keys.

MR. DALY: Good afternoon, your Honor. Jim Daly on behalf of Abbott Laboratories.

MR. TORBORG: David Torborg, also on behalf of Abbott Laboratories.

MR. WINCHESTER: And Jason Winchester for Abbott.

MS. WITT: Good afternoon, your Honor. Helen Witt on behalf of the Roxane defendants.

MR. GORTNER: Good afternoon. Eric Gortner on behalf of Roxane defendants.

MS. REID: Good afternoon, your Honor. Sarah Reid on behalf of the Dey defendants.

MS. LORENZO: And Marisa Lorenzo on behalf of the Dey defendants.

THE COURT: Weren't there more people?

MR. HENDERSON: That's it, I think, for counsel.

THE COURT: All right.

MR. HENDERSON: Your Honor, I want to apologize on behalf of all parties, all counsel, for raising some false hopes that we'd have an agenda for you today. I think I can speak on behalf of all counsel. We did confer in the spirit of cooperation, but there are many issues. Every party has its own agenda, so --

THE COURT: Well, let me just ask you this. As I understand, the only case we have comes out of Florida? Or is there a separate case out of Massachusetts?

MR. HENDERSON: That's a loaded question, your Honor.

THE COURT: In other words, is this case going to trial in Florida?

MR. DALY: The Abbott case is, your Honor.

THE COURT: Abbott is. Are any of the others not?

MR. HENDERSON: Let me clarify. Dey and Roxane

are here before your Honor for all purposes.

THE COURT: Dey and Roxane are here for all purposes?

MR. HENDERSON: Yes. The United States may well seek to transfer the Abbott case from Florida to your Honor. That would be a future matter, and I'm sure it would be disputed by Abbott.

THE COURT: Well, I ask that because I did not finish reading all the briefs. It was overwhelming, overwhelming. You had all begged for these long page limits, and I had assumed it was because you had to go through different states' laws. It got very repetitive, and there would be some new issues nestled in one or the other. I mean, despite three days of reading, I didn't get through it all. So the issue is, at the end of the day, I don't know how much we're going to accomplish today and whether I'll need a second day.

Now, the second thing is, if it's my case and I'm going to keep it and try it, it's a jury trial. Everyone agrees on that, right, it's a jury trial? I don't know that I need to write extensively. I mean, you all want me to find summary judgment on elements. You don't find summary judgment on elements. You find them on claims. Or you want me to find summary judgment on two years out of a ten-year spread. I'm not sure why I should do that.

There are a couple of crosscutting legal issues, to the extent I got through all the briefs. There was a due process challenge. I think that's a question of law, and I should probably do something with that. There may be a relation-back issue, those kinds of things. But you're all asking me to dissect this element by element and year by year in terms of summary judgment, and I don't know why I would do that.

That's my overarching question to all of you: Why should I spend six months reading through all these briefs, which have made it as complicated as possible? Why doesn't it make more sense for me to just rule on the overarching legal issues and rule on the remainder of them after I finish the trial? I have to deal with a Daubert issue on damages, I think. I think I have to deal with the spoliation issue, the due process issue, and maybe the relation-back issue. But I think the government wants me to rule element by element, and typically one doesn't do that in summary judgment if you're not going to resolve a whole claim.

MR. HENDERSON: Well, I understand, your Honor. Rule 56 does permit the Court to rule on less than all of a party's case.

THE COURT: Oh, definitely, but typically not element by element.

MR. HENDERSON: Well, in our case, we moved for summary judgment as to liability on certain aspects of the case. Today that's what I'd like to focus on.

THE COURT: Well, let me ask, the government knowledge is a defense, isn't it?

MR. HENDERSON: Yes, asserted by the defendants.

THE COURT: Right, so you want summary judgment on that?

MR. HENDERSON: Yes.

THE COURT: So, I mean, that's a defense. I imagine that's okay. But I had thought you were asking for summary judgment element by element.

MR. HENDERSON: Well, we would like summary judgment on the falsity of the prices. We think those will be important for going into trial.

THE COURT: So even if I think that the government knowledge defense and knowingness are interrelated, you would still want something on the falseness?

MR. HENDERSON: That's correct.

THE COURT: I don't know. I mean, one is overwhelmingly tempted, rather than reading the -- how many pages of briefs all together?

MR. HENDERSON: Probably 600 or something. There was plenty.

THE COURT: I gave it plenty of time all weekend,

last night, the night before, and I have not finished it. And I found so much of it redundant that what I was looking forward to today is to have people just start distilling the key issues they feel I need to resolve.

MR. HENDERSON: Well, and probably what's going to happen today to a certain extent, your Honor, is the parties will be ships passing in the night arguing different issues that they'd like you to address.

THE COURT: So what would you like? I'm telling you where I need some help. It's clear that there are some key overarching legal issues, and I don't know that I'm going to want to go through the boxes of documents and deal with every single one. I think it makes more sense for me to learn the case and try it.

MR. HENDERSON: Well, I'll tell you what I'd like to start off with, and that is really where --

THE COURT: So do you want half an hour, and then you get half an hour, and then we'll see where we are on the overarching issues? Does that make some sense?

MR. HENDERSON: A half an hour will just barely touch on --

THE COURT: Well, what do you want? What's your dream organization? You know, like, help me here because I do know that usually the individual briefs are just little cleanups, and they weren't here. There were whole new

issues on the individual briefs. I mean, I'm going to have to do a half an hour and a half an hour for each company.

MR. HENDERSON: What I'd like to do, your Honor, is have about forty-five minutes to focus on where about 80 percent of the money is at stake here. Of the three cases we've got, we've got single damages of about $1.4 billion.

THE COURT: 1.4?

MR. HENDERSON: Billion.

THE COURT: I thought I heard the B word. All right, so that's crosscutting issues.

MR. HENDERSON: Well, I'm just putting this in perspective. Right today, I want to go for where the money is, and 80 percent of that, your Honor, is in Medicare on one drug, ipratropium bromide.

THE COURT: All right, so I just want to get a game plan for today. So you'd like to spend how much time on your core dollar --

MR. HENDERSON: Forty minutes, forty-five minutes.

THE COURT: Okay. And that's going to hit all these crosscutting issues?

MR. HENDERSON: No.

THE COURT: So you're not helping me here.

MR. HENDERSON: It's going to hit where the money is on Medicare on a summary judgment area that I think you

can and should decide because it's pretty narrow. The First Circuit has cleared away a lot of the brush.

THE COURT: Well, I can't spend forty-five minutes on ipratropium bromide, so why don't you do this: I'm going to give you half an hour for starters just to talk, and then I'll give -- it's your drug, right?

MR. DALY: No. The one Mr. Henderson is talking about is not.

THE COURT: Who's the deep pocket here on the ipratropium bromide? She stands.

MS. WITT: We both are, your Honor.

THE COURT: You both are, okay. So then maybe we'll give you a certain period of time to respond, and then see how much time is left and start moving to some of these crosscutting issues. Does that make sense?

MR. DALY: Well, Judge, I mean, from your comments, I mean, I tend to agree with where you seem to be coming from initially, which is that the Court has looked at summary judgment in the Mylan case, for example, and found that you couldn't enter summary judgment on scienter, and therefore that was it. And I don't know -- I'm not sure what we're doing here in the sense that the arguments that the government is making are, "Let's decide this issue." It's like a motion in limine in the guise of a summary judgment motion: "Don't let them use this evidence."

Well --

THE COURT: Yes, but the big difference with Mylan is, that was a WAC case where WAC wasn't as well defined, whereas AWP is clearly false. So, I mean, I can parse the apple that way.

Let me do this. You aren't helping me at all. I have a sense of the issues. The government will do forty-five minutes focusing on what you want, what you think is most important, and then you'll do forty-five minutes on what each of you thinks is the most important, and then I'll see what else I need. I don't know how else to do it. You're not helping me.

MR. HENDERSON: And I understand your Honor's frustration, and if we have time, which I hope to, we'll address the Medicaid issues, which are more difficult crosscutting issues, but, quite frankly, the Medicare program in this drug account for nearly 80 percent of the dollars in this case.

THE COURT: Okay, so go ahead.

(Discussion off the record.)

THE COURT: Mr. Henderson, I'm just going to give you till 3:00 o'clock, and then I'll give opposing counsel a certain period of time, the remaining time, and we'll see where we go from there.

MR. HENDERSON: Very well. Thank you.

MS. REID: Your Honor, Sarah Reid. I wanted to introduce. I have not had the honor of appearing before you, so I --

THE COURT: Well, welcome to the crowd.

MS. REID: Thank you. I just wanted to say, and we can proceed, that when we conferred on the agenda, the defendants' belief was that today's hearing would focus on common issues on the government's side, a common presentation on the defense side, and then with each of us speaking to what we thought were common issues. So it comes as something as a surprise that today's hearing from the government's point of view is going to be on ipratropium bromide. That's fine, we'll deal with it, but it's likely that our presentations will be more focused on what we believed to have been the agenda for today, which was the common crosscutting issues.

MS. WITT: Your Honor, and if I might just supplement, we also believed that we had an agreement with the government that the issue that relates to the NovaPlus, which is a specific Roxane issue, would also be put down to the bottom of the agenda.

THE COURT: Well, is NovaPlus ipratropium bromide?

MS. WITT: Correct, and we will deal with that today because it's a huge part of the --

THE COURT: Well, I asked everybody to send me a

game plan, and no one has. And I kept saying to Mr. Alba, what do you want to do, what do you want to do? So I can't rule at this point. I'll let you each use your time as you want, and then you're just going to have to suffer if I get it wrong.

MS. WITT: Thank you, your Honor.

THE COURT: All right?

MR. HENDERSON: Our summary judgment on this particular piece of our case is limited to liability, not damages. It focuses on one Medicare carrier, a DMERC, Cigna, which is for Region D. It covers a specific period of time, which will be clear in a little bit, covering the second quarter of 1997 through the third quarter of 2001. Our complaint covers a broader period, up through the end of 2003; but, as you'll see, our motion for summary judgment is more narrow, and I do suggest that this piece of our case is a bellwether that will clarify and focus the trial issues.

Very briefly --

THE COURT: I'm curious, why didn't you tell them this is what you were going to do?

MR. HENDERSON: Well, we debated back and forth how much would be spent on common issues, how much would be spent on separate issues.

THE COURT: But did you tell them you were going to make this your flagship?

MR. HENDERSON: I told Mr. Gortner that I was expecting to spend a fair amount of time on that after we failed to get agreement.

MR. GORTNER: I will respectfully disagree with what Mr. Bunker is representing. We spoke, and the agreement that I understood is that we would discuss on crosscutting issues and common issues, and that there was some particular Roxane-specific issues, the NovaPlus and ipratropium bromide issue and an alterego issue that both the government and myself and Roxane representatives agreed was best served for a subsequent company-specific, shorter hearing, and that was my understanding that we had reached an agreement.

THE COURT: Well, I wish you had focused them on it and me because, truthfully, I've spent hundreds of pages on it, and I would have focused on this piece of it myself.

MR. HENDERSON: And I hope to have time to cover the Medicaid piece, but, your Honor, if I spend time on Medicaid --

THE COURT: No, excuse me. But you should let me know. You don't understand, each of you, on the major briefs, there were a couple hundred pages just on the initial briefs coming out of it, not to mention the replies and the surreplies. There must be 500 or 600 pages' worth of briefing on this. So anyway, I mean, go ahead.

MR. HENDERSON: Okay. On the issues of falsity, your Honor, I don't know if you can see the first slide here.

(Discussion off the record.)

MR. HENDERSON: Just so your Honor understands the spreads --

THE COURT: Now, what's this? What am I supposed to be looking at?

MR. HENDERSON: This is -- is it not on your screen?

THE COURT: It is, but where is it in here?

MR. HENDERSON: Okay, this is Tab A.

THE COURT: Okay.

MR. HENDERSON: And I'll go much faster if I can just rely on the screen, your Honor, because these graphs, we'd really have to find them.

This is a graph prepared by the government's expert accountant, Mr. Simon Platt. It's an exhibit before the Court in which Mr. Platt has taken the transaction data, internal transaction data from Roxane, summarized it and compared it to the published prices.

At the very top, the top blue straight line, that is the published AWP for Roxane's ipratropium bromide product. The red line is their WAC, which is irrelevant for purposes of Medicare because Medicare did not use WACs.

They just used published AWPs. And the yellow line that gradually gets lower is Mr. Platt's calculation of the actual average prices at which Roxane sold in its indirect sales to the retail pharmacy class of trade.

And the next slide is a numerical quantification of these spreads. Roxane had three different products, ipratropium bromide products, three different package sizes. Here is their package size of 25s and their package size of 60s.

Now, let me capture a little bit more of this so we can see the AWP spread, which has been calculated in accordance with your Honor's instructions in the multidistrict case. We can see that the spreads start, the AWP spread over on the right starts at about 77 percent at the time Roxane launched this product in 1996; and through the end of our summary judgment time period in late 2001, the spread was up to about 400 percent. Our complaint goes through the end of 2003 where it gets up to 500 percent. And those figures are roughly consistent amongst all of its ipratropium bromide products.

Roxane admits that they reported their AWPs to Red Book, and I refer the Court to Paragraph 18 of our statement of facts and Roxane's response where they effectively admit that they reported these AWPs to the Red Book.

The picture with Dey is essentially the same. We have graphs prepared by our expert which show the spreads on the ipratropium bromide products.

THE COURT: Where is this? Still in A?

MR. HENDERSON: No. This would be in B, which is a copy of Mr. Simon Platt's declaration in the Dey case. And both in Roxane and Dey, he set forth the spreads, calculations of the spreads.

Again, here at the top we have the AWPs as reported by the Red Book. We then have the WACs, which in the case of Dey declined over time. And then there are the actual average sales prices calculated from Dey's transaction data.

And, similarly, Mr. Platt prepares calculations of the AWP spreads. Dey entered the market for this drug in 1997. They were the second entrant after Roxane. Their spread at the time of launch was approximately 129 percent. By late 2001 or during 2001, it grew to about 238 percent and kept on growing after that.

And similar spreads exist for the other ipratropium bromide package products. They, like Roxane, had package sizes of 25 vials, 30 vials, and 60 vials. And these graphs, they're all pretty much the same in terms of characterizing the spreads.

And Dey, as in the case of Roxane, Dey does not

dispute that they reported AWPs to Red Book, and Red Book published those AWPs. And I'll respectfully refer the Court to our Paragraph 58 of our Rule 56 statement of facts and Dey's response, and also Paragraph 142 and Dey's response, in which they acknowledge that when they launched in January of 1997, they provided an AWP of $44.10 to First DataBank and Red Book, which was published by those databases.

The government's position, as set forth in our brief, is that because of these spreads, these mega spreads way in excess of any 30 percent speed limit, establish essentially, under the Medicare program, falsity. And neither of the defendants present any evidence to dispute these basic facts. They present lots of legal arguments, which I hope to get to.

I do want to talk a little bit about causation. As your Honor knows, Medicare Part B used the Healthcare Common Procedure Coding System. They used HCPCS codes. Ipratropium bromide had two codes. Throughout the time period, Medicare Part B paid the lower of the amount billed by the provider or the allowed amount calculated by the DMERC carrier. The allowed amount calculated by the DMERC carrier, before January 1, 1998, was 100 percent of the median AWP of the generic products, unless there was a brand. If that was the only one there, they would set it at the brand AWP.

After January 1, 1998, and after the Balanced Budget Act of 1997, the allowed amount calculated by the DMERC was 95 percent of the median AWP, or, if there was a lower-price brand AWP, they would set it according to that brand AWP.

The DMERCs typically created arrays in which they did these calculations, and in the declaration of Carolyn Helton, the first page of which is here on this screen, Ms. Helton sets forth how she did her pricing determinations, including the arrays that she on behalf of --

THE COURT: Which tab is this now?

MR. HENDERSON: This would be C.

THE COURT: Oh, so I'm just going in order?

MR. HENDERSON: Yes, I'm just going in order. Hopefully it will all work out.

THE COURT: All right.

MR. HENDERSON: And I wanted to give you a few examples of some arrays so your Honor can understand how this worked. I will skip to this array which is part of this same exhibit. And this is an early array, handwritten, and this only has -- this was before our summary judgment time period. This would be in Ms. Helton's declaration somewhere, at the ECF Document No. 308-4, or Page 22 of 74. And here the only product in the array is the brand product, which is not the subject of our complaint, so we don't seek

any liability or damages for pricing, for payments made on the basis of this array.

When we go to the next quarter, which is the second quarter of 1997, here we can see an array that's been put into a spreadsheet format that she uses. You can see that both Dey and Roxane's generic products are in the array. The package price -- for example, the Dey of $44.10 is the AWP price for that first product -- has been converted to a price per milligram so that there is just one common measure. And the median is calculated at $3.52. That's a median calculation that was constant throughout the time period that our motion focuses on.

I will then jump to the last --

THE COURT: So how did she calculate this?

MR. HENDERSON: She took the median of the price per milligrams. And since they're essentially all the same, it's pretty easy, $3.52. And at this time, payment was based on 100 percent of the median AWP, so Cigna paid claims at $3.52 per milligram for this drug, ipratropium bromide, unless the provider charged a lower amount.

THE COURT: Well, how many other people manufactured ipratropium bromide?

MR. HENDERSON: At this time the only other manufacturer was the brand product Atrovent, so at this time only Dey and Roxane were in the generic market.

THE COURT: Well, why wouldn't its brand, if it had been accurate, have brought it lower?

MR. HENDERSON: If an accurate AWP for the brand had been lower, it would have determined the allowed amount. We haven't sued for that product. It's not part of our case. We have no proof as to what their actual acquisition costs were. We don't have any proof that their AWP was false.

THE COURT: Well, tell me, so what if Dey's price had been accurate?

MR. HENDERSON: The declaration of Ms. Helton states -- she has reviewed all of the arrays for this summary judgment time period, and she states that any reduction of the Dey products of 1 percent or more would lower the median, and therefore the allowed amount; and similarly, with respect to Roxane, any reduction in the AWPs of 1 percent or more would lower the median and the allowed amount.

THE COURT: So you all are looking for the increment of the 1 percent?

MR. HENDERSON: No. We're just saying we have established falsity and causation. We will leave damages to another day. But the fact that any reduction would lower the allowed amount establishes, in our view -- well, the falsity is established by the spreads. The causation,

causation is established by the fact that any reduction of 1 percent or more of the Dey drugs will establish causation as to Dey, and as to the Roxane drugs, any reduction of 1 percent or more.

So this Court does not have to decide what is the appropriate "but for" AWP. You don't have to decide what's the appropriate spread, speed limit. All of our drugs have spreads way in excess of 30 percent. And so any reasonable reduction, any reasonably honest AWP would have affected the median. So we're not asking the Court to determine damages for us. So that's why I think this piece of our case -- and we're just talking -- this looks like $3.52 as opposed to $1.70 or something, but when this is multiplied out through the case, the effects are very substantial.

I would like to jump to the last array in this time period, which is the third quarter of 2001. You can see on the screen, your Honor, this is a more sophisticated array. It's in a spreadsheet. Almost all of the arrays in this case were produced in electronic format, and therefore it's actually rather easy to substitute different numbers to see what happens, and I'd like to do that with a replicate of this array in Excel format.

THE COURT: Where is this?

MR. HENDERSON: This is a replicate of what you just saw.

THE COURT: What I just saw was what number so I can follow it? In other words, Mr. Henderson, I'll never remember this tomorrow.

MR. HENDERSON: That's right. This is a replicate of the page marked Page 35 of 74 of the same --

THE COURT: Thank you.

MR. HENDERSON: And for your information, in the bottom right-hand corner of the document is a footer, which was actually added for purposes of litigation, which shows the electronic production pathway, just for purposes of all parties to show exactly where that is, but that footer also identifies the year and the quarter when the array was in effect.

In this particular replication that's on the screen, your Honor, I've eliminated a few or I've hidden a few columns so everything can fit on one page so I don't have to be looking around too much. But you'll see the cursor is on Dey's product, first product, package of 25s. And if that is lowered to just $3.50, and I do that for each one, you can see the generic median here where I have the cursor went down from $3.52 to $3.51.

The brand names are shown in this lower panel. The lowest brand is $3.52, which is Roxane's ipratropium bromide NovaPlus drugs, but the allowable amount has changed to $3.51. And the same is true if we changed the numbers

for Roxane products: Just lowering them by two cents would change the median and the allowed amount.

Now, this impact exists, as I said, up through the third quarter of 2001. A declaration of Ian Dew -- let me just refer your Honor to the language of Carolyn Helton's declaration where she says -- I'm sorry -- with regard to both companies, that for this period, any reduction of 1 percent or more in the AWPs of the Dey products would lower the median and the allowed amount. The same is true as to the Roxane products.

And our consultant Ian Dew prepared a summary of the claims data. The claims data of the Cigna DMERC Region D claims for this product shows that about a million claims were paid by Cigna for ipratropium bromide; and of those, approximately 90 percent, over 900,000, were paid at either $3.52 or 95 percent of that $3.52, which is $3.34. The rest of the paid claims, approximately 10 percent, were paid at an amount consistent with the provider's charged amount.

Now, we have not moved for summary judgment for the time period after 2001 quarter three. At that point in time things are a little bit different, and I'm going to come back to this same spreadsheet and illustrate this because Dey has moved for summary judgment on a piece of the case which relates to our view that the combined impact of

Dey and Roxane must be considered.

In short, after the third quarter of 2001, we can change the AWPs of Dey down to a penny, and it doesn't change the outcome, the median calculation. We can change the AWPs of Roxane down to 1 cents, and it still doesn't change the median calculation. However, if we change the AWPs, if we lower the AWPs of both Dey products and Roxane products by 1 percent or more, it does affect the median.

And I think it's helpful to see why this happens, and what I'm going to do is go to a replicate of the next quarter when things change. This array is virtually identical with one exception: Apotex has entered the market with a new product. We can see that their AWP for a package of 25s is fairly high. It's $4.48, which is higher than the Dey products and the Roxane products.

Now, under Dey's theory of the case on which they seek summary judgment, because there is one more company that has entered the market with an inflated AWP, according to Dey, the United States cannot recover a penny because Dey's products in isolation do not affect the median; likewise, Roxane products in isolation do not affect the median; and, according to their view of the case, the United States' ability to prove damages and recover evaporates because one additional company has entered the market. And I would suggest to your Honor, that just cannot be. We have

clearly demonstrated that these companies --

THE COURT: Well, couldn't you get penalties anyway?

MR. HENDERSON: Yes.

THE COURT: So why does -- I mean --

MR. HENDERSON: The False Claims Act allows us to recover our losses.

THE COURT: When you say you can't collect a penny, I mean, wouldn't knowingly false presentation of claims money create a penalty situation even if you can't prove damages?

MR. HENDERSON: Well, that would be our position. I'm sure the defense would argue that there's no causation because it wouldn't have affected the amount of the claim.

THE COURT: So you still need the causation, even if it's completely false?

MR. HENDERSON: We would probably have a disputed legal argument on that, your Honor, but I think it's evident that we have proven this demonstrates that Dey and Roxane combined have a large impact on the allowed amount. And the law doesn't leave us without a remedy for these losses, putting aside the civil penalty issue. The Restatement of Torts, Section 442-A, Comment D, I'll just read it for you, your Honor, quickly: "A force due to an act of a third person, which is wrongful toward another who is harmed, may

be only a contributory factor in producing the harm. If so, both the actor and the third person are concurrently liable. This is true although the actor's conduct has ceased to operate actively and has merely created a condition which is made harmful by the operation of the intervening force set in motion by the third party's negligent or otherwise wrongful conduct."

And then it goes on to say, your Honor, "However, while there is concurrent liability, the two forces are not concurrent causes, as that term is customarily used. To be a concurrent cause, the effects of the negligent conduct of both the actor and the third person must be an active and substantially simultaneous operation."

And here we have the effects of the wrongful conduct of both Dey and Roxane in effect in simultaneous operation affecting the outcome of the median calculation.

Just so I can highlight to you --

THE COURT: You know, I struggled with this mightily in the big class action suit.

MR. HENDERSON: Yes, I'm aware of that.

THE COURT: I struggled with it, and there were no good cases on this. There's that sort of abstract Restatement of Torts language. It's a very hard issue.

MR. HENDERSON: Well, in that case, of course, your Honor only had one company before it, and there was

proof of liability only with respect to one company; and when you substituted the arrays in that case, it didn't change the median. And in fact we followed that approach in the case of Dey with respect to its albuterol drug, a same drug. We didn't sue all of the other parties in there. And the damages we've calculated against Dey are very small, tens of thousands of dollars.

THE COURT: You're saying the difference here is, there are two fraudulent actors, if you will?

MR. HENDERSON: That's correct, and we've proven wrongful conduct on the part of both of them, and their combined impact establishes/demonstrates a big loss. And there can be no question, your Honor, that the Medicare program suffered substantial losses as a result of the combined impact of false pricing.

THE COURT: Okay, since we only have ten minutes left, why don't you deal with the purple elephant in the room, which is the government knowledge defense. Does that apply to this drug?

MR. HENDERSON: Well, we're talking about the Medicare context, so I suggest the government knowledge is really resolved to the government's favor by the First Circuit's recent decision, in which they effectively upheld your interpretation of "average wholesale price." Certainly all the government knowledge --

THE COURT: Well, that's absolutely true, they did. On the other hand, I didn't deal with -- I don't remember whether ipratropium bromide was on a list in the OIG reports and whether or not there was a DOJ price for them. I mean, it was different in those branded drugs factually, not in terms of the standard but factually.

MR. HENDERSON: I understand, your Honor, and there have been -- there was one OIG report focusing on ipratropium bromide.

THE COURT: In what year?

MR. HENDERSON: I think it was the early 2000s. What was the year? 1998? Okay, I'll take Roxane's word for it.

THE COURT: And what does it do? It lists the true price?

MR. HENDERSON: It indicates -- it evaluates the discounts that were available in the market and discusses that the AWPs for ipratropium bromide were inflated.

THE COURT: At the levels that you have them in that graph? Do you remember?

MR. HENDERSON: I don't recall. There are some significant inflations there. But let's assume for argument that the OIG understood at that time and had some specific evidence that there was inflation in ipratropium bromide prices. Obviously, the government does not agree that an

OIG report that is critical, is certainly not accepting of these or approving of these inflated prices -- in fact, they're complaining about how much this is costing the Medicare program. And I can't remember exactly when a FUL was ultimately put into place for the Medicaid side. And as we know, there's a whole history. Ultimately the Department of Justice tried to get this pricing information changed. It was withdrawn, there were Congressional hearings, and ultimately we got the reform of the MMA.

It is the government's position that government knowledge when the defendants, they acknowledge that they never -- they never read any of these reports or relied on them in making their pricing determinations. We saw in those prices, those AWPs stayed the same the whole time period. And the evidence is overwhelming that the motivation in setting those AWPs was to create an attractive spread so that their products could be successfully marketed to providers.

So, yes, there was evidence indicating that OIG knew that AWPs were inflated for ipratropium bromide products, but that is not a defense. That sort of government knowledge does not at all establish government approval of this. In fact, just the opposite. The government people who were investigating this were complaining about it --

THE COURT: The standard is in a statute, isn't it, that it's got to be AWP, 95 percent of AWP?

MR. HENDERSON: That's correct.

THE COURT: That's a statute at this point, right?

MR. HENDERSON: That's correct. And the statute had a plain meaning, in our view, and this Court decided that correctly.

So that's our simple response to the government knowledge evidence presented by the defendants.

I will just point out so that your Honor is aware the NovaPlus issue. We're not really prepared. I mean, we can discuss it, but I don't think we'll have time to really to discuss that. But on this chart, just changing one price here to about 75 cents, which was the approximate real average sales price that our expert uses marked up by 25 percent, you can see the dramatic impact that that has. All of a sudden the allowable drops way down to 71 cents.

THE COURT: Because that's a brand?

MR. HENDERSON: Because it's a brand. And the real impact of that is nearly $500 million. Of that change, when it's made all across the DMERCs --

THE COURT: All the DMERCs or just the one?

MR. HENDERSON: The four, not just this one.

THE COURT: All right, so NovaPlus involves all --

MR. HENDERSON: Yes, we've moved for summary

judgment only as to one.

THE COURT: Why?

MR. HENDERSON: One DMERC.

THE COURT: Why?

MR. HENDERSON: Why? Because if we multiplied our proof by four, you would just be overwhelmed. I just think it's -- there's too much paper.

THE COURT: So Cigna is just the biggest pot?

MR. HENDERSON: No.

THE COURT: Or it's the clearest evidence?

MR. HENDERSON: It's just straightforward. At the time we were preparing our motion for summary judgment, we were just wary of loading you up with too much stuff.

(Laughter.)

MR. HENDERSON: So we picked one DMERC.

THE COURT: So are you seeking to extrapolate from that one DMERC?

MR. HENDERSON: No.

THE COURT: So that's not part of this extrapolation defense.

MR. HENDERSON: No.

THE COURT: That's only in the Medicaid area?

MR. HENDERSON: Yes. There is some extrapolation on the Medicare side in the Abbott case. For Dey and Roxane, ipratropium bromide, there is no extrapolation. We

have the arrays. There are very few arrays, maybe six or seven or something, maybe ten or so that are missing; but you look on either side of the array, and there's really no doubt as to what the array consisted of. So it's not an extrapolation.

THE COURT: So prioritizing my time, you want me to look at this issue?

MR. HENDERSON: Yes, your Honor. It's a lot of money, and I think mixing some judgments on falsity and causation here will really advance the ball, both in terms of settlement, quite frankly, hopefully --

THE COURT: But I'm not sure why it will. I understand why it might give you money, but some of the toughest issues, as I read it, are the "lower than" and all the different Medicaid methodologies and the issues of extrapolating data from ten states to all of them. Those are incred- -- this won't help with that at all.

MR. HENDERSON: No. They're different issues.

THE COURT: Big different issues. So, I mean, if I rule on this, you just get a big quick bang for your buck, but I still have to work through all the other ones. It doesn't help me on any of those.

MR. HENDERSON: That's correct. We just don't have enough time today to work through all the issues, but this is a big-money issue, and I thought it was important

for the Court to look at.

THE COURT: Okay. Well, thank you for that.

So, now, how do you want to handle this? It's now 3:00 o'clock. Do you each want half an hour? Do you want one crosscutting one and then short ones for each of you separately?

MS. WITT: Your Honor, can we have 90 seconds to just confer among the three of us because this is different from what we expected?

THE COURT: Yes, go. That's fine.

(Discussion off the record amongst defense counsel.)

MR. HENDERSON: If I could, just a point of clarification, your Honor? That presentation addressed the regular ipratropium bromide products. We really didn't focus on the NovaPlus issues, which are separate, pretty much separate. I illustrated at the very end, but I didn't want you to be confused, that in the top part of that array, the Roxane and Dey products were their normal generic ipratropium bromide.

THE COURT: Well, at what point did the NovaPlus product come into play?

MR. HENDERSON: That came in I think around 1999, a little bit later, 2000.

THE COURT: Well, why as soon as that came in,

assuming Roxane was unlawful, why aren't they the primary cause of the problem as opposed to Dey because they've got the brand?

MR. HENDERSON: In our view, they are. They are. However, let me point out that if for some reason -- I will say that their utilization under Medicare was very small, a hundred prescriptions probably filled under Medicare. So that there is an issue that Roxane says is completely unfair because the utilization was so small, and yet it makes a difference of like a billion dollars. It's a huge difference. If --

THE COURT: All right, I get it. I've got to give them their time. I understand.

So what are you doing?

MS. WITT: Your Honor, what I was going to do is have Mr. Daly talk about some of the crosscutting issues, which we do think are applicable, even to the presentation that Mr. Henderson just made, because they relate to issues that were not mentioned in his presentation -- in particular, scienter -- and also address some of the issues that we believe make this case very different than the other cases that you've considered, make the 30 percent yardstick that you determined as a trier of fact after a full record not the appropriate yardstick in a generic case. Ms. Reid will then talk about the specifics of ipratropium bromide.

THE COURT: Well, you're looking for me just not to grant summary judgment at all, pretty much, other than on a few narrow issues, or do you differ on that? You just want a trial?

MS. WITT: Certainly we want summary judgment not granted on any of the issues that the government had raised. Each of us has very specific issues that are not anywhere close to the crosscutting issues. For Roxane we have --

THE COURT: But all of you agree, as I read it, that something goes to trial?

MS. WITT: Correct, correct. And Ms. Reid will talk specifically about the ipratropium issue and government knowledge to respond directly to Mr. Henderson, and then Mr. Gortner will talk about the NovaPlus issues, because they really are the big gorilla in terms of the damages number, and why it's a billion-dollar case and not in the thousands-of-dollar case. So that's where we think our time is most productively used.

THE COURT: All right. So, Mr. Daly, I'm hoping what we'll do here is go for about a half an hour with you, and then we might have to take a break for the court reporter.

MR. DALY: Certainly, your Honor.

THE COURT: And I will say that before we leave here, there are three things that I'd like to accomplish:

the date for the Daubert hearing on the damage expert, a date for the spoliation, and a tentative trial date so I can get everybody in the same room, at least for the ones that are mine. You'll have to worry about the Florida one later.

MR. DALY: Judge, we did come in wanting to talk a little bit, I think, about the crosscutting issues because I think they do go to all of our motions. Just to clarify, nothing that Mr. Henderson was talking about relates to Abbott. That's not our drug. Also, for Abbott, the government has not moved for summary judgment on any Medicare issues. Their issues are only Medicaid when it comes to Abbott, as well as the Medicaid issues against our codefendants. And I think, as the Court has observed in other contexts, it's our position that that's going to require -- as I think Mr. Henderson said, you get into a lot of issues when you talk about Medicaid. Well, that's right. We think it's a 48-state-plus-DC-type issue where each state's system is going to have to be looked at, and --

THE COURT: How come no one briefed? The only reason I gave in to everyone's demand for these lengthy briefs is because you represented to me that you had to brief all these states, and that in fact never happened.

MR. DALY: I believe the government took that tack, your Honor, because I think when you look at each of the states -- the government's position here is, you know,

all this great discovery that we've done for the last two or three years, that's all good, it doesn't matter, it's irrelevant. They want to try this case regardless of whether anybody was misled, regardless of whether anybody was fooled, regardless of any --

THE COURT: You know, without the rhetoric, though, the False Claims Act is different from 93A and the fraud claims. It's statutory. It's different.

MR. DALY: Yes, but it's not a strict liability statute, your Honor. You still have to prove falsity, causation, scienter, materiality.

THE COURT: Well, scienter is knowingly rather than an intent to deceive.

MR. DALY: Correct. But our position on this -- what we'll want to talk a little bit about is some of the differences between the three cases that are in front of you now and what you've looked at before, and then we want to talk about expectations when it comes to generic drugs. Your Honor has not had a generic drug case yet, and we want to spend a little bit of time talking to you about --

THE COURT: I've had Mylan.

MR. DALY: Well, I don't think that was really in the generic world. That was a WAC case.

THE COURT: It was WAC.

MR. DALY: These are cases, Judge, where we're

talking about generics and the very different expectations that are out there in the states, at CMS, in the state Medicaid agencies. In terms of Track One -- well, let's talk about, first of all, Dr. Hartman. Dr. Hartman gave you in T One a 30 percent speed limit. That was based entirely on brands. He testified that "I don't have an expectations yardstick for generics." And what the government has done -- and they don't have anybody in this case that's before you, any of these three cases, who comes forward and says, what are the expectations on brands? They don't have an expert. They don't have lay testimony. They don't have any testimony whatsoever. They don't even posit what the expectations should be with respect to brands.

And even Dr. Hartman testified, when he talked about 30 percent, he said, "With generic, it's even a lot more than that, but I haven't been asked to do that." Dr. Schondelmeyer, the expert that they have in this case, does not have an expectations yardstick for any of these defendants. He says expectations for generics were much, much higher than they were for generics, but the government doesn't do anything with respect to it.

And what the First Circuit did when it affirmed your Honor is, it didn't affirm on the plain-meaning interpretation that the Court gave. It affirmed on the expectations issue, and talks about how the expectations in

the industry, the expectations at CMS, the expectations at the state level are the things that matter. And the government gives you absolutely nothing on that issue. You don't know from their briefing what New York expected, what Illinois expected, what California expected. They don't bother with any of that. And I think what you heard from Mr. Henderson is, well, it's 30 percent. Well, it isn't 30 percent because expectations -- and the J & J situation was remanded to your Honor to look at the expectations of Class 1 with respect to the drugs there. What is expectation other than a question of fact? What did people expect? What did CMS expect when it comes to generics and the spreads that are involved here? What did the state Medicaid agencies expect when they looked at these generics?

And there are categories of generics that are even more important. For example, Abbott has infusion drugs. The drugs at issue here are infusion drugs. They are drugs that are used for I.V., dextrose, saline, sterile water to deliver other kinds of drugs, things of that nature. There's overwhelming evidence in the record that everybody at the CMS level, at the state level, you know, the pharmacy directors, all knew that with respect to Abbott's infusion drugs, the spreads were even greater than what they expected with generics generally, which are all greater than what was expected with respect to branded drugs. So you have very

particularized situations about what people were expecting in this area when it comes to, A, generics in general, and, B, the defendants' drugs in particular.

THE COURT: In the big case that went up to the First Circuit, the problem is, that was a 93A case.

MR. DALY: Yes, your Honor.

THE COURT: And this is a False Claims Act case.

MR. DALY: Yes, your Honor.

THE COURT: So the standard there was, was what the company did outrageous, egregious, beyond the pale of what's acceptable ethical conduct? The False Claims Act is different.

MR. DALY: Well, yes, it is, your Honor, and I think that what we would say -- well, we think --

THE COURT: That's why expectations were so essential in the 93A case, and it's completely different here. The False Claims Act is pretty -- you just go through this check list. Was it a false price? Yes. Was it knowing? Yes. Did it cause damage? Yes. But then you have a very strong argument: But the government knew about it.

MR. DALY: Right, and we think --

THE COURT: So that's different than -- you know, the case law is varied on that. Some go so far as to say that mere knowledge isn't enough; you have to actually have

approval. And others say, well, acquiescence is enough. So, I mean, I have to play with that sparse area of law. But it's different because it's your burden to prove it. It's an affirmative defense, as I understand it.

MR. DALY: Well, but our view is that expectations goes to falsity. Expectation goes to scienter as well.

THE COURT: Well, it's really not an average wholesale price. What your argument is, "But everyone knew it."

MR. DALY: Well, it's more than that, Judge. It's not that everybody knew it. Our proof, the proof that we have in our briefs is not that everybody knew it; this was policy. We have evidence, and we can go through it, and I will go through it --

THE COURT: Fine, fine, I'll grant you policy. It's a false price which you say the government acquiesced in because of countervailing policy reasons with respect to access. It still comes up in that way: Did the government know and either implicitly or explicitly agree to it? That's the issue.

MR. DALY: That's one way of looking at it, yes.

THE COURT: It is the issue. It's an affirmative defense.

MR. DALY: Well, but why isn't it part of falsity, is our position? Because if somebody says something, says X

to a person, and that person knows that that's not true, it goes to falsity.

THE COURT: It's false, but the person doesn't reasonably rely on it. If somebody said, "That carpet is blue," that's false. I just would be an idiot to rely on it.

MR. DALY: Well, I think that what the cases talk about, Judge, is that --

THE COURT: Although sometimes patent lawyers can --

(Laughter.)

MR. DALY: I think a patent lawyer would tell you it actually is blue, Judge.

THE COURT: They say the lens and the spectrum. They get you to believe it. But the reality is, that's how I'm thinking about it, which is to say that carpet is blue would be false, but if I bought it anyway, you would have a defense because I bought it knowingly.

MR. DALY: Well, and the question is, and if I tell you it's blue, and because I already know that you know it's not blue, do I have the appropriate scienter? I mean, and what the cases say is that scienter and falsity blend together. And Boese speaks to this a lot, and I know your Honor has looked to Boese a lot when it comes to the False Claims Act. He talks about how you can't really separate,

and we have a lot of cases that we cite in our brief that talk about not being able to separate falsity and scienter here. And I disagree. I don't think false --

THE COURT: Well, sometimes that might be the case.

MR. DALY: Right.

THE COURT: And the reason I denied summary judgment, if I'm remembering correctly, in Mylan is, it was a WAC-based case -- I sometimes blur these cases, I have so many of them -- and it wasn't a hundred percent clear that people understood what WAC meant. But here AWP under any theory, it wouldn't be, right, an average wholesale price under any theory? It couldn't possibly. Everyone agrees. That's the one thing that's come across. Everyone agrees it has no relationship to the marketplace, so it's plainly false.

Your argument, which is strong, is: Sure, but the government knew it and continued to use it. And so that's a defense. And then I have to decide, is it enough to be approval or acquiescence for policy reasons?

MR. DALY: Yes, and I think, you know, I don't think we need a hall pass from CMS or the government to do it. In other words, it doesn't have to be they write us a letter, "Go ahead and do this."

THE COURT: I agree, I agree.

MR. DALY: Right. But I still want to hang onto the notion that the knowledge, the expectations, and the policy go to falsity and scienter as well because that's what the cases seem to suggest. If you have an ambiguous term -- and I need to stop Mr. Henderson short. We don't have a plain-meaning interpretation of AWP in the Medicaid world.

THE COURT: Medicaid we don't, but I thought the First Circuit -- I didn't read it the way you did, and I certainly -- I thought the expectation piece went to the outrageousness of the conduct one way or another, not to the meaning of the term. But in the Medicaid world, AWP might mean different things. I've just never seen it, at least in Massachusetts, which is the one I sort of explored, intended to mean something that was unmoored to the marketplace.

WAC is harder because it doesn't say "average," and it's a wholesale acquisition cost, and do you mean an average? Do you mean a median? Does it include the discounts and rebates? What if there's a pass-through? I mean, you could see where there would be some confusion perhaps on that. You know, is it undiscounted or discounted? Is it the list price of 80 percent of the people who use it and not 20 percent? But AWP is an average of wholesale prices.

MR. DALY: In the Medicaid world, Judge --

THE COURT: In the Medicare world.

MR. DALY: Right, in the Medicare world, you've construed that, although it was on a different record than the record we have here. In other words, one thing to remember in these cases, another reason why these cases are different, Judge, is, in T One when you did that, the government asserted the Touhy regulations. You didn't have any testimony from the government witnesses that we had here. What you had was the government's amicus brief where they told you what they thought that the Secretary understood and believed. We've now gone and deposed all those people, and they say that none of that is correct; none of them understood and believed that AWP meant actual average wholesale price.

THE COURT: McLellan said it in my case, the other one, the class action, the former administrator of CMS.

MR. DALY: Right.

THE COURT: So let's not go down that road.

MR. DALY: But the point I'm trying to make is that your Honor says, well, it's false. Well, we don't know it's false because in the Medicaid world, we have a lot of states that actually define AWP in their statutes. You don't hear any of that from the government.

THE COURT: Okay, so that's where I need -- that's where I thought I'd get briefs on it.

MR. DALY: The government doesn't want to bother with that. They just want to say, "Ah, it's false. You've already decided it."

THE COURT: Neither did you. Neither did you. I don't know how I'm going to do this. I expected my 600 pages of briefing would actually help me through the state statutes, which is why I allowed so much.

So tell me a state. Give me an example of a state where AWP is defined not to mean some estimated acquisition cost.

MR. DALY: Judge, take a look at Tab 18 of the document, the notebook I handed to you. This is just some of the examples, Judge. And what I want to say about this is, the government moved for summary judgment here. It's their burden to come in --

THE COURT: I'm not sure these examples do it for you.

MR. DALY: Well, but what they do, Judge, is they say they're all "as set forth in the compendia, as set forth in the compendia." We have testimony that goes along with this, Judge, that says where these people fully understood that the compendia prices were not actual acquisition costs. Nobody thought it was actual acquisition costs. And what we have is situation after situation of government policy where you have these state Medicaid agencies sitting around

saying, okay -- For example they've got --

THE COURT: Excuse me. Are these statutes?

MR. DALY: Yes, your Honor.

THE COURT: So that turns out to be the same issue, which is, again, it's the government knowledge defense that they knew, and they bought anyway, and they acquiesced in it, they affirmatively acquiesced in it in order to woo providers to stay in the system because the dispensation costs were --

MR. DALY: Yes, the dispensing fee, sure.

THE COURT: I mean, it's the same issue, isn't it?

MR. DALY: It is. I think we differ. I believe, A, it's an affirmative defense; B, it really does go to falsity and scienter as well. In other words, you can't just simply say something is false when somebody knows that it's not true. It goes to the issue. This is what Boese talks about, this is what a lot of cases talk about in terms of being unable to separate the elements of scienter and falsity in an area like this, particularly when you have an ambiguous term.

And another thing that the First Circuit did, another thing that Professor Berndt did in his report to you, the term "average wholesale price" is ambiguous. The First Circuit says it's -- if one thing is clear from all this, the meaning of it is unsettled. Berndt said in his --

THE COURT: You know, I think you misread that case, but we can go on on this. So one big issue you have is government knowledge defense, and you want trial on that. So give me the best evidence you have about why the federal government acquiesced in it. Let's just --

MR. DALY: All right, but I just want to clarify one thing, Judge. When I say it's unsettled, the point I want to make is that under the False Claims Act, when you have a statute that admits of more than one reasonable interpretation, it's very difficult to assess False Claims Act liability, not because -- well, because it goes to the falsity and scienter points. In other words, if the defendant can show an interpretation that is reasonable and rational, and if others can show alternative interpretations of that phrase, it's very difficult to assess -- this is a penal statute, it's a punitive statute. It's treble damages plus penalties. It's very difficult to do that.

THE COURT: I understand your point, but I'm not going to accept that these prices anyone understood to be an average wholesale price. Now, I've been dealing with this for eight years now. Maybe I'm wrong.

I am somewhat, and that's why I'm moving you on here a little bit, sympathetic to the fact that at some point the OIG started flagging these discrepancies. They started telling the world that there were these huge

problems with generic drugs.

So now the issue is, CMS is stuck with the statute which says 100 percent of the median AWP or 95 percent of the median AWP. And you claim at some point what, that they -- they don't have to turn on a dime. There's a statute that requires it. So it can't be that the first OIG report that comes out, bingo, gets you off the hook. You're saying, though, at some point over time they acquiesced affirmatively as opposed to being horrified. Is that what you're saying? There was an embracing of the drop for policy reasons? Isn't that your argument, that they --

MR. DALY: Well, and the question is -- you know, you found a perfect storm for branded drugs in 2001. We all want to push that storm a lot further back in time.

THE COURT: Right, so help me with that. That's your big argument, which is how far back would you say that there's a viable government knowledge defense? It can't be the minute Ven-A-Care brings a complaint because they're supposed to investigate.

MR. DALY: I think it's before that, Judge.

THE COURT: Oh, before.

MR. DALY: Long before that.

THE COURT: So help me.

MR. DALY: Take a look at Slide 9 that I gave you, your Honor. This is the testimony of Bruce Vladeck. This

is the CMS administrator, the head of the agency from '93 to '97. And we deposed him, and he's talking about -- we're talking about infusion drugs here. That's Abbott's drugs, the ones that I've been talking about. And he's saying, "I recall monthly headlines in Modern Healthcare about group purchasing operations being -- achieving discounts of 98 and 99 percent in their purchase of basic infusion products and sterile supplies." That's our situation.

And then he continues, "List prices are essentially -- are entirely meaningless."

And then we ask him, "Well --" and this is an example of some of the spreads on an Abbott drug, for example, where it says, "Would you be surprised if one person can get it for $10 and another person with bargaining power can get it for $1? Answer: I would not be surprised." And that's a 900 percent spread.

So this is the head guy for CMS putting knowledge of what your Honor calls "mega spreads" on infusion drugs back in the 1980s. This is the head of the department.

Now, another thing to keep in mind here, and another point that I think has gotten lost when we move to the area of generics, is that we have witness after witness who says: People spend dollars, not percentages. And so when we depose all these state Medicaid agencies, they talk about wanting to make up for the inadequate dispensing fees

by overpaying for the drugs. And what we have in that situation is that they want to pay them money.

So in Abbott's case, AWPs are mostly, you know, below a couple dollars and the costs being 24 cents. So we're talking about pennies here, and we're talking about -- whereas, in your opinion in T One, you approved spreads over $200, so -- because they were within that 30 percent thing that Hartman gave you in that case. Whereas, in our case, we have a spread of like $1.71. And it might be 200 or 300 percent, but it's a dollar. And what the state witnesses say over and over again is: People spend dollars, not percentages. So that what you need to do -- and let me get that GAO thing --

THE COURT: All right, so that struck me in your brief that that's in defense of the Medicaid claims, and so for how many states do you have those kinds of comments?

MR. DALY: How many states do we what?

THE COURT: Have comments like that from the Medicaid administrators?

MR. DALY: For virtually all of the ones that we did, and we did most of them.

THE COURT: So you have a comment from a state administrator in every state basically that they knew that there was the spread, and they did it for policy reasons?

MR. DALY: Virtually, Judge. We didn't depose

every state. I mean, we had to make concessions to time.

THE COURT: Well, how many states did you depose?

MR. DALY: How many did we do?

MR. TORBORG: About thirty.

MR. DALY: About thirty, your Honor.

THE COURT: Thirty? And so you would say that you have that, and is that somewhere --

MR. DALY: We have similar testimony.

THE COURT: That's somewhere in this massive -- so it's clear to me that you have that for every state?

MR. DALY: Yes, and we can give you the cites. I think we've collected that in a couple of paragraphs that I can give you momentarily.

THE COURT: And what about with CMS, do you have quotes like that coming out of CMS? "We knew that there was a spread, but we thought we needed to do it for dispensing fees?"

MR. DALY: Well, what we have out of CMS is a little different. What we have is, in the Medicaid world -- remember, CMS approves all the state plans. So we have document after document, and some of them are in the book that I have gave you, where the state, you know, wants to -- OIG does a survey, and they say, well, generic drugs of 85 percent below AWP, and here is Illinois, they want to do AWP minus 11 as their reimbursement level for generics.

And what happens is that CMS looks at this and says: Well, we understand that. We're having difficulty getting the states to set the reimbursement levels in accordance with what the invoice studies are showing. But what they keep telling us is that the dispensing fees are inadequate. And so what the states are doing is, they're overpaying or paying more for the drugs; and because the dispensing fees are inadequate, and, you know, enough of this is happening, that, by God, we're going to let them do it.

THE COURT: So you have CMS documents that say that or witnesses?

MR. DALY: Take a look, Judge, at 31. Judge, what this is, this is a GAO report where they talk about meeting with HCFA, and they said, "HCFA also noted that because states focus on reducing Medicaid costs, most state programs are not willing to increase dispensing fees, regardless of survey results. HCFA and state Medicaid officials agreed that pharmacies must often use excess Medicaid reimbursements to cover their dispensing costs."

THE COURT: So you would say that would be a defense to the federal portion of the Medicaid claims?

MR. DALY: Absolutely.

THE COURT: Now, what about with Medicare?

MR. DALY: Well, they're not moving against Medicare against Abbott, first of all, but in the Medicare

world, Judge, I think what --

THE COURT: Maybe it would be fairer to leave it to people --

MR. DALY: Well, this is where we've got to go into the world of expectations, and I think expectations is related to knowledge. It's related to government knowledge. It's related to the defense. It's also related to the elements. And what the witnesses say in this case over and over and over again is that the expectations for these drugs are much higher.

No one is surprised. No one at CMS, and we have a lot of witnesses in that regard, and no one at the state level is surprised that there are large spreads here. And what the evidence shows and what these documents shows over and over again is that what the states were doing was intentionally paying more for the drugs than what they knew to be the acquisition cost, what they did from their own surveys and what they were getting from OIG. We have state after state that says, "I understand that. I understand that the drugs cost less than what I'm paying for them, but I've got this problem on the dispensing costs. And I hear what you're saying. I have your DOJ AWPs, which, by the way, have Abbott's drugs on them. I see what the actual prices are. I know that, but I hereby choose as a matter of policy to pay AWP minus 10 or AWP minus 15 percent as a

matter of state policy because I need to keep people in the program, and I need to make up for what are clearly inadequate dispensing fees." We have a lot of documents, even in what I've put in front of you, Judge.

THE COURT: Thank you. So, now, it's 3:30. She's been going since 2:15. I'm thinking we'll take a fifteen-minute break or so.

How much time do Dey and Roxane need?

MS. REID: Well, your Honor, given that we're the focus of the argument --

THE COURT: You're in the cross hairs here.

MS. REID: -- if I could have a half an hour, I would appreciate it.

THE COURT: I don't think we're going to have time. Well, we could give you each a half an hour.

MS. REID: Yes, each would be --

THE COURT: But is it the same argument?

MS. WITT: No, your Honor. We're going to talk specifically about NovaPlus. What that will leave at the very end of the time then will be the alterego motion that was filed by Boehringer Ingelheim Pharmaceuticals, Roxane's sister company, and Boehringer Corp.

THE COURT: I'm not going to have argument on that.

MS. WITT: Well, we'd appreciate an argument on

another day because it is --

THE COURT: Maybe, maybe. I'm much more focused on -- why does that really matter at this point?

MS. WITT: Because the Department of Justice's position is that those companies are liable for the $1.5 billion for the ipratropium bromide.

THE COURT: Is it a piercing the corporate veil?

MS. WITT: It's a piercing the corporate veil primarily.

THE COURT: I didn't get to that, so let me just --

MS. WITT: We don't need to deal with that today, but I did --

THE COURT: That I haven't read yet, so I'm sort of focused more on these pricing issues. So we'll come back around quarter of, give you each sort of, let's say, twenty minutes each so there's enough time here, and then some response, I think is probably what we're going to have to do. Okay, we stand in recess.

(A recess was taken, 3:30 p.m.)

(Resumed, 3:50 p.m.)

THE COURT: All right, so go ahead.

MS. REID: Thank you, your Honor. I will try and be brief and as direct as I possibly can, and I want to hit just a series of points and then finish with the ipratropium,

which I know was the focus of Mr. Henderson's comments.

First, your Honor, not to belabor the point, but as my brother Mr. Daly said, the generics industry is different. It does not work like the branded industry. The expectations yardstick of the 30 percent that Professor Hartman put before your Honor doesn't work in the generics industry, and the whole understanding of the industry and how the term "AWP" is used is totally different. And I think that it's in that context that it's important, you know, to understand that your Honor needs to hear the evidence at the trials of how the generics industry operates because it gives context to whether or not the participants in that industry believed they were doing anything that would come afoul of the False Claims Act.

Turning to the next quick subject, you had asked, again, "Mr. Daly, the evidence that you have that it's a policy decision on the state level?" And I would just point very quickly that you have a document which was attached as Exhibit C to defendants' surreply, a July 28, 2008 e-mail --

THE COURT: Which defendants' surreply?

MS. REID: We did a joint one. It was only 12 pages your Honor, so --

THE COURT: I never got to the surreplies.

MS. REID: The surreply is 12 pages. It was good and short. And the only reason that this was attached so

late, your Honor, is because these documents were withheld on a claim of privilege for over a year, and Magistrate Judge Bowler just recently ruled they were not, so we could use them.

Mr. Dubberly said, "In declining to join AWP litigations, the AWP calculation methodology has not been set forth in any statute or government guidance. Therefore, a claim that an undefined calculation methodology is unfair or misreported is not one --"

THE COURT: Could you start again. Who are you reading?

MS. REID: This is the attachment to the July 28, 2000 e-mail --

THE COURT: Could you put it on the screen just so I can read along with you.

MS. REID: We don't actually have it on the screen. We can give you a slide of it if --

THE COURT: Who are you reading? Who are you quoting?

MS. REID: Jerry Dubberly.

THE COURT: Yes, but who is it?

MS. REID: He is the head of Pharmacy from the State of Georgia's Medicaid agency.

THE COURT: So this is Georgia's person?

MS. REID: Georgia. They never joined. They have

not sued. And the reason they didn't sue is --

THE COURT: Well, if they didn't sue them --

MS. REID: Well, the federal share is before your Honor, but the state share, the state government has never joined because, in his view, "A claim that an undefined calculation methodology is unfair or misreported is not one that the department can support." So that's Georgia.

You have as we speak and as we had filed --

THE COURT: About which drug?

MS. REID: At all.

THE COURT: But generics, brands?

MS. REID: Both. I mean, actually the document in question says that they've underpaid on generics and overpaid on brands, but I don't go into that. The document in its entirety is attached to the surreply as Exhibit C, Docket 6567.

Again, the State of California this year, there is presently in the Ninth Circuit an injunction affirming the issuance of a preliminary injunction against Medi-Cal prohibiting further reductions in it's compendia AWP discounted by 17 percent formula because of concerns over access, where the Ninth Circuit says --

THE COURT: Wait. The cite is what?

MS. REID: The cite is to Independent Living Center of Southern California, Inc., the David

Maxwell-Jolly, 572 F. 3rd, 644.

THE COURT: And who is it against? Who's he, the administrator of Medicaid?

MS. REID: Yes, against Medi-Cal, the administrator, July 9, 2009, where they basically say -- and it included pharmacies -- that they would not allow a further reduction by 10 percent "because there is a robust public interest in safeguarding access to healthcare for those eligible for Medicaid, whom Congress also recognized to be the most needy in the country."

Again, this is a plan in 2008 that CMS approved with an AWP on a compendia basis.

And, finally, as your Honor knows, and I don't wish to discuss at great length because it's a complicated decision, but we did file yesterday Docket No. 6599, the Alabama Supreme Court reversal of three jury verdicts in cases brought by the Alabama State Attorney General on brand -- it was a brand case, not generics -- noting, the court, that the decision --

THE COURT: That was there was no reasonable reliance case?

MS. REID: It's a fraud case.

THE COURT: Yes.

MS. REID: But what it said was, it could not have been clearer that the state as a policy matter "determined

the inappropriate reimbursement formula based on its own surveys and calculations in order to balance the twin goals of expenditure and to insure pharmacy participation." The court noted that the amicus brief of the National Community Pharmacy Associations said that, at the levels of the proposed, you know, acquisition costs that are being discussed, and even as we speak today, would have caused Alabama Medicaid to essentially collapse. And since there was no indication in the record that Alabama Medicaid wished to discontinue its Medicaid program, they, you know, did not consider that to be, you know, what was the actual intent. So --

THE COURT: Is Alabama one of the states here?

MS. REID: Alabama's federal share is. And, of course, that leads to the whole state-share issue. The federal government, as I understand, has asked Alabama for any shares of any settlements, and it all becomes very complicated. It's a very significant decision --

THE COURT: Is that res judicata on the Alabama claim?

MS. REID: That's a very interesting question. It's one that I think may require further thought and briefing as to what the preclusive effect of that opinion is.

THE COURT: So it would only bind with respect to

Alabama. I mean, I think I have to do this in all fifty states, or whatever states the government is seeking damages for.

MS. REID: Your Honor, I think that we all need to read that case carefully, and I don't know that I can commit one way or the other. I just found it -- I thought that your Honor should have that case because it is from the highest court in Alabama, and I do think it is going to have significant --

THE COURT: Law.com got it to me, so thank you.

MS. REID: Before we did? So that's on the Medicaid side, and I just wanted to point --

THE COURT: I want you to know, that case got more publicity in twenty-four hours than my eight-year case has probably gotten --

(Laughter.)

MS. REID: There is no fairness. There just is no fairness.

But let me go back now to Medicare because your Honor asked for the evidence that was collected, and we have collected in the defendants' common statements of fact, at Section C beginning at Paragraphs 104, federal testimony on the meaning of AWP which may be helpful, and it includes the testimony of the administrators. And you heard Mr. Daly quote Mr. Vladeck, who was the administrator in the 1990s,

but --

THE COURT: Excuse me. I'm not changing my definition of AWP. It's a matter of law, plain language. I'm not changing it. That's an appeal issue that's gone up.

Now, that's different from what you maybe knew or understood. It's different from whether there was an intent to deceive or defraud. It's different from whether the government deliberately veered off the course of that definition, but I'm not changing.

MS. REID: Your Honor, I respectfully understand that. I would note that the First Circuit in the context of the case before it said it was not reaching the plain-meaning definition because --

THE COURT: I am not reaching it again either, okay. I'm not touching it. WAC is different, but AWP, don't waste your breath. You're preserving the issue. But that's different than state of mind, I understand that, so --

MS. REID: But I would just point out because you asked, in the Medicare context, you know, what was in the mindset? Was there approval? Was there knowledge? You know, when you have the CMS administrators all saying, among others, "Have you ever heard anybody else who used AWP to refer to the price at which a pharmaceutical firm or wholesaler sells a drug to a retail customer?"

"Mr. Scully: No."

I understand your Honor's position, but I think in the record --

THE COURT: I'm not changing it. But what I do think it may be relevant to is what the government knew and whether they acquiesced in a different price.

MS. REID: Right.

THE COURT: So I just don't want to waste time now because there's so much for us to do.

MS. REID: Let me go quickly then to the next point, which is, in the case of Dey and also Roxane, you're dealing with inhalation drugs. It's a very different thing than the Abbott drugs, and there are different dispensing fee issues. And I would note that at the time that the MMA was enacted, the dispensing fees changed dramatically for inhalation drugs. They raised them to $57, then ultimately lowered it back down to $33; but the bottom line was, they realized that these types of drugs, particularly as they were administered often through home healthcare, had higher dispensing costs.

THE COURT: So how much of a spread would it take to compensate for that dispensing fee?

MS. REID: It's really the dollars, not the spread. I mean --

THE COURT: Well, just I'm saying, your big

argument, which has some support in the record, is that they deliberately, "they," the government officials, deliberately shut their eyes to the spread because they understood the dispensing fee was too small. So what was the dispensing fee? It was what, like $8 or something.

MS. REID: It was about $5 --

THE COURT: $5.

MS. REID: -- in prior. And in our expert's report, you know, Dr. Bradford goes through showing that ultimately -- it is a more complicated answer than you're going to want, I think, to hear in this short time, but what happens is, you initially go from a low dispensing fee, high ingredient cost. You then go down to a much lower ingredient cost, higher dispensing fee. Dispensing fee begins to come down, but then what you find is, in the inhalation drug area, you start seeing compounded drugs that are being dispensed rather than just plain, you know, individual ipratropium or albuterol. So that ultimately the Medicare reimbursement level and the amount of dollars does not really go down that much. In fact, it's interesting to see that progress, and it's something that I think at trial --

THE COURT: I know, but you're right, that's more complicated.

MS. REID: I know, so --

THE COURT: Let me just ask you this: Your big argument is that the government deliberately yielded to these spreads to subsidize dispensing costs. So I need some evidence about, what kind of spread are we talking about that you'd need to do that?

MS. REID: Well, in terms of the actual amount, I would say, you know --

THE COURT: Maybe you don't have it in the record. Maybe that's why you say I need a trial, but --

MS. REID: In terms of the amount, I can't give you a mathematical figure at this point in time.

THE COURT: Do any of these documents do it out?

MS. REID: No, because the OIG reports never looked at the dispensing costs, with the exception of ones out of Chicago where they would say that in order to actually look at the whole thing, you've got to look at the rebates, dispensing costs, and ingredient costs. But in the reports that are primarily before your Honor, they're only looking at ingredient costs. But what I think in terms of, you know, looking at the issue of --

THE COURT: Would the extent of the spread end up in, you know, like $100 for a dispensing fee when the only reasonable one would be $33? Has anyone done the math or any expert looked at it?

MS. REID: I think our expert on the inhalation

context has looked at the generic industry and has looked at the progress. I mean, I don't think there's anybody out there who can say to you what the absolute kind of Aquinian true price should be for any particular drug at a point in time. It is, after all, a competitive --

THE COURT: You're not hearing me at all.

MS. REID: I'm sorry.

THE COURT: So when you're saying dispense a drug, is that the pharmacy?

MS. REID: Or it could be the home healthcare administrator.

THE COURT: Or the home healthcare. So what does it mean to dispense the drug? Does it just mean for a woman to go count 20 pills, and she then puts it in a bag? What are we talking about?

MS. REID: The dispensing cost is supposed to cover the cost of, in this case, the pharmacy, you know, to some extent its overhead. I mean, when you look at the Myers & Stauffer's report, that's what they go through: the employees' salaries, the overhead, the cost of keeping the pharmacy in business in essence. When you look at the home healthcare administrator, it's a different --

THE COURT: But is it more for your drugs than for other drugs?

MS. REID: I don't think that's always true. I

think he would say the infusion drugs, it's even higher.

THE COURT: What do they pay in dispensing fees now under Medicare?

MS. REID: Under Medicare and for our inhalation drugs, I think they are higher.

THE COURT: I found that a very difficult piece of the record because while it may be true, as it was in the other case, there was some cross-subsidization, it was pretty clear that 30 percent did it in the branded drug world, and that any argument that the 500 percent was necessary was ridiculous. But now we're in generics. But no one's pride me the actual dollars and cents about what it would take to cross-subsidize for the real cost of dispensing. Is it the 1,000 percent spread you're talking about, or would it be a 200 percent spread?

MS. REID: Your Honor, you have to look at the pharmacy in question --

THE COURT: No, you don't.

MS. REID: -- at the different class of trade.

THE COURT: No, but you have to set policy. So obviously someone was setting this policy that a certain percent is what was needed to keep the pharmacies in the system, right? Someone made that decision, that's your theory of the case.

MS. REID: Right.

THE COURT: So do we have those calculations somewhere so that we know what their expectations were?

MS. REID: In the Medicaid context, I think you do have much more because you have a lot of the states that have done the actual surveys and reports, which were the Myers & Stauffer's reports of what is the acquisition cost, what should be a normal dispensing fee, recommendations on that.

THE COURT: So where would I find it because it wasn't really briefed that way?

MR. DALY: Judge, if I may on the Myers & Stauffer?

THE COURT: Yes.

MR. DALY: If you look at Tab 17 in what I gave you, Judge, this is one example, and this is about infusion drugs. And Myers & Stauffer, by the way, they go out and they do a lot of surveys of states. They're also the DOJ's consulting expert in this case, but they end up being a fact witness. This is the report, and we have another one at Tab 34 for Louisiana. But looking at California, what it's saying is, "In every dispensing cost survey, the provision of this service, home infusion," Abbott's drugs, "of this service has been associated with higher dispensing costs. Dispensing costs range from $20 to $40."

And in this particular document, what they're

doing, Judge, is, they're saying -- California is thinking about changing, and what Myers & Stauffer says in the third call-out is that if you keep it at AWP minus 5 percent, which is what you do in California, "it is estimated that such an average prescription would yield a margin on ingredients of approximately $42." So if you keep it at AWP minus 5, you'll be paying your pharmacist a profit, an intentional profit of $42. "This margin typically allows for adequate reimbursement of dispensing costs"; in other words, the 40 bucks that it actually cost to dispense this kind of drug.

So what Myers & Stauffer, the DOJ's consulting expert, says, is, "So long as the ingredient reimbursement rate remains at AWP minus 5 or any other relatively high level," I mean, if you keep it high, "then the need for the department," California, "to set a separate dispensing fee --" in other words, increase your dispensing fee, you don't have to do it because you're paying them 42 bucks which covers it.

THE COURT: Good. That's the kind of thing I was talking about.

MR. DALY: Okay.

MS. REID: Your Honor, I've been advised -- and we'll got the cite for you -- there is the GAO 2001 report which attempted to look at dispensing fee costs for

inhalation drugs and found a range which, you know, ranging from over -- I'm not sure the bottom range, but up to somewhere in the 50s. We will supply that cite to you and reference, if that would be helpful.

THE COURT: But no more briefs.

MS. REID: No more briefs, I promise, I promise.

THE COURT: Okay, go ahead.

MS. REID: Let me just quickly turn to the ipratropium and the OIG information regarding Dey's ipratropium and the various ipratropium reports. All of them are in the record. Particularly Dey's statement of fact 128-131 is comparing starting in 1998, comparing drug reimbursement, Medicare and Department of Veteran Affairs, which found the median prices versus the Medicare allowable, and had with it -- actually, Dey's actual invoices were part of the working papers on that. January, 2001, Medicare reimbursement of prescription drugs also dealt with ipratropium. No. 3, excessive Medicare reimbursement for ipratropium bromide, March, 2002. No. 4, update January 20, 2004, on excessive Medicare reimbursement for ipratropium. In the working files for the early reports, not only were there invoices, there were Federal Supply Schedule prices --

THE COURT: All right, so let's take that they knew. Let me just say, in the Medicaid context --

MS. REID: No, that was Medicare.

THE COURT: I understand. In the Medicaid context, there's some evidence that they knew and they agreed to it to subsidize dispensing fees. So it was more than just knowledge; that they sort of held their nose and did it because they thought it was the right thing to do to provide access. Do you have any such documents in the Medicare area?

MS. REID: In the Medicare context, your Honor, it's the actions. It's the program memoranda. It's the fact that they instruct their DMERCs to use the compendia prices at the same time that they know that these compendia prices are inflated. Their 30(b)(6) witness testified that the only thing that constituted government knowledge was the regulations in the program memoranda and the statute. And they conceded that they continued to use the compendia price, to direct the DMERCs to use the compendia price, although they knew that the AWPs were, quote/unquote, "inflated." They issued that program memoranda --

THE COURT: And they say that in the depositions, "We did that even though we knew"?

MS. REID: Yes. I mean, not -- in the two that we talked to. I mean, they know the prices. In the case of Dey, at the same time that they are publishing their AWP, which they believe to be their generic entry-level price benchmarked to tell people there's a generic on the market,

Dey is publishing -- in the same publications, declining WACs, which show the prices are going down. They're giving CMS the AMPs, which turn out to be, the price is very close --

THE COURT: AMPs are a little different but --

MS. REID: But, you know, this is CMS.

THE COURT: This isn't "should have known."

MS. REID: But they did know.

THE COURT: Right, it's got to be "did know," and did know affirmatively and acquiesced. So that's what I need. I need maybe not, as you say -- it was a very good metaphor -- maybe not a hall pass, but they had to do more than just know.

MS. REID: But the AMPs were sent in to the CMS, the very people who, you know -- I mean, your Honor, it was public knowledge. The FSS prices were publicly available.

THE COURT: So when was the first time that there was a public report about the ipratropium bromide?

MS. REID: It was 1998, and for Dey's other drug, albuterol, it's even earlier. It's '96.

THE COURT: And when were these launched, in 1992?

MS. REID: Albuterol launched in like '92, and ipratropium for Dey launched in '97. So within a year, in both cases, the government has got reports out that the ingredient costs were in both cases Dey's actual invoices

costs in their records.

THE COURT: Those are the hard issues here. Thank you.

MS. REID: Thank you, your Honor.

MS. WITT: Your Honor, I just want to direct the Court's attention to two specific documents that are on the same issues that Ms. Reid just talked about on the same issues, and then Mr. Gortner will talk briefly about the specific issue on NovaPlus. And both of these documents we do have some slides for that I won't put up, but we'll hand them to the government and your clerk with the citations on them. One deals specifically -- and I acknowledge completely at the front that it's a 2008 document, and it's dealing with Medicare Part D. It's Roxane's statement of facts, Paragraph 97, Tab 126.

THE COURT: It's a what?

MS. WITT: It's a Medicare Part D document.

THE COURT: What year?

MS. WITT: 2008. But the significance of the document is that it is very explicit when evaluating the issues of spreads that it's finding in Medicare Part D, that "They encourage the use of generic drugs, since their use provides good value to both the beneficiary and the taxpayer, and we note that the incentives are aligned to encourage promotion of generics by community pharmacies."

Now, the significance of the language there that the incentives are in line is its reference to the spreads, the different profit margins the pharmacies are making on generics because the spreads for the generic drugs are, relative to the spreads of the brand drugs, large enough that a community pharmacy will use a generic drug, so that the government still ends up paying less for the drug than it would if it were paying for the brand. So it's a point that we see less directly, a lot more subtly in the Medicare documents earlier than this date, but the practice was exactly the same; that the spreads in the generic drugs provided an incentive that still saved the government money. So that there was a lot of, in addition to the acknowledgment of the spreads and the knowledge, there's a lot of looking the other way on the generic size of the spread because of the dollar amount and because of the incentives.

THE COURT: That's a legal question, though. Looking the other way may not be enough. Affirmatively embracing will be enough. Acquiescence, I don't know what it is.

MS. WITT: Well, your Honor, if looking the other way is embracing and acquiescing without saying, "We are embracing and acquiescing," because that runs into a huge battle of another sort, but if you say, "Here's what the

spreads are for these generic drugs, and you know what, this is a good thing and it's a positive thing for the program overall because --"

THE COURT: Okay, I've got the argument. Thank you. So what are the next --

MS. WITT: And then the other one I just want to direct your attention to is the CMS approval of state plans. And this is a critical document, which is Roxane Exhibit 128, because it shows the federal government looking at what the states are doing and saying, "You know what, sometimes the states want to pay more than what we know based on the surveys is the actual acquisition cost, and they have all these negotiations --"

THE COURT: What's the date of this document?

MS. WITT: This is a 2002 document. "We know that the states are negotiating with your their pharmacy associations. We know that there's political issues here in the states, so we're going to approve their state plans, even if their state plans come to us and say, we want to pay more than the acquisition cost." And the specific guidelines that are incorporated in this document explicitly say, "We are going to tell all of these regional offices to approve it if the state thinks it's good for them."

THE COURT: Thank you.

MR. GORTNER: And, your Honor, I'd like to speak

just briefly on the NovaPlus issue. I have a couple of handouts I'll refer to, if I may approach.

THE COURT: I have a confession for you first.

MR. GORTNER: Okay.

THE COURT: I didn't get to NovaPlus. I got to most of these other issues but not this one, so --

MR. GORTNER: Well, it might be useful then to give you a broad overview of the issue, since it gets somewhat complicated in the briefing.

Your Honor, you earlier saw from Mr. Henderson an array where one of the DMERCs, at least, had put the NovaPlus ipratropium bromide product in the brand array. Now, the evidence here is that this product has always been considered a generic product by just about everyone except --

THE COURT: You can have -- can't you have branded multi-source?

MR. GORTNER: Yes, and I will talk in a moment about the branded multi-source, but let me explain why this product falls under the generic category.

Now, in this situation, the undisputed evidence is that Roxane always considered this to be a generic drug. It named it "ipratropium bromide," which is the generic chemical compound name. It's an inhalation drug. The addition of the term "NovaPlus" at the end referred to --

unlike the ipratropium bromide Roxane-labeled product, the NovaPlus product was sold only to Novation GPO members, which were hospital members, and they needed some way to be able to identify the difference between the Roxane ipratropium bromide and their ipratropium bromide. And as I'll show you in a moment, every other generic ipratropium bromide in the marketplace was also called "ipratropium bromide," the generic chemical name. The brand was called "Atrovent," nothing related to the generic chemical compound name, like Valium or Tylenol versus acetaminophen or ibuprofen.

Now, what has occurred in this case, as you may recall, is that these NovaPlus drugs were added at the close of fact discovery at the very end of the case because during the course of fact discovery, what we found out was that some of the DMERCs had classified the ipratropium bromide NovaPlus product as a brand, and others had classified it as a generic. And during the course of the deposition testimony, Mr. Henderson, during the questioning of one of the DMERCs, even said, "Now, I'll represent to you, Ms. Eiler," which is one of the DMERC representatives," that NovaPlus actually has always been a generic product, not a brand product." And he went on to say, "In fact, the NovaPlus NDCs are generic drugs, and if you'd done some additional research," DMERC, "besides looking just at the

Red Book, you might have determined --"

THE COURT: Well, did the Red Book call it a brand?

MR. GORTNER: If you turn quickly to Slide No. 2, what I handed you, your Honor, this is a printout from the Red Book CD that the Department of Justice claims that all the DMERCs were looking at to classify the NovaPlus ipratropium bromide product as a brand or a generic. And if you look at the highlighted yellow portion there -- this is just a printout from the screen they had available to them the whole time -- it has a specific generic indicator, a "yes" and "no," and it indicates "yes," this is a generic product, not a brand product.

Your Honor, in our papers and in the undisputed record, First DataBank also classified it on all six of its generic indicators as a generic product.

Now, this is consistent with all of Roxane's behavior here. They called it after the generic chemical name. The AWPs were set identical with the Roxane-labeled product that no one disputes is a generic product, the same 10 percent off the brand AWP. The NovaPlus product had those same AWPs. The contract prices were the same or lower than the Roxane-labeled generic product. So simply put, there's nothing here in the record for them to establish causation, and these are catastrophic type of damages

they're talking about.

THE COURT: Well, why isn't this just a fact dispute?

MR. GORTNER: Well, because, your Honor, under the False Claims Act, they have to be able to establish proximate causation here. They have to be able to establish --

THE COURT: No, no, no, wait a minute. Whether it's a generic or a bromide -- maybe I misspoke -- why isn't that a fact dispute someone would have to resolve at trial?

MR. GORTNER: Well, your Honor, again, there is -- with respect to what it actually was, the issue that has to occur here is whether it was foreseeable to Roxane. That's the evidence they'd have to show up here. It may have turned out that under some particular view of the world, it may have been considered by somebody to be a brand, but the issue here to establish treble damage causation --

THE COURT: What does brand mean? It means -- I mean, now that I'm forcing myself to think about it, branded means -- typically in my previous litigation it meant it was subject to a patent and had a name on it, a specific, you know, selling like Lipitor or Claritin or something like that.

MR. GORTNER: Exactly, and that is --

THE COURT: So you have a specific name on it, and

you're saying that's not enough to give it a brand.

MR. GORTNER: Well, no. I mean, one issue, you raised the issue of the patent, your Honor. The patent on Atrovent, the brand expired in 1996. The Roxane label "ipratropium bromide" came on the market in June, 1996. Dey came in 1997. This product didn't enter the marketplace until mid-1999. It didn't show up in the arrays and the DMERCs until 2001. By the time it's --

THE COURT: You're saying there's no difference between this product and your generic?

MR. GORTNER: No, it's the exact same product. There's the generic ipratropium bromide --

THE COURT: Well, why did you put a brand name on it?

MR. GORTNER: Well, your Honor, it's not a brand name. We put "Ipratropium Bromide Inhalation Solution 2 Percent" on it. The "NovaPlus" addition is the identification of a label. It would be the same if we put "Ipratropium Bromide Roxane" or "Ipratropium Bromide Dey." It identifies whose label, whose product it is. It doesn't identify -- it's a completely different issue than a proprietary name like Atrovent or Valium. I mean, it makes no --

THE COURT: This is a proprietary name, though, right, because you called it "NovaPlus"? So I guess the

question would be, would that be enough to transform it into a brand if it's the exact same ingredient as everything else?

MR. GORTNER: It's identical, and if you turn to Slide 4, your Honor, this is the slide that lists the Red Book CD printouts of all the ipratropiums. And what we've done is, we've put in red "Atrovent" which stands out as a brand name product, a proprietary name for the product. And then we also have listings in green is the Roxane-labeled product, and in yellow is the ipratropium bromide.

THE COURT: Is Atrovent yours? No.

MR. GORTNER: Atrovent is Boehringer Ingelheim.

THE COURT: Who's your sister company?

MR. GORTNER: Is a sister corporation with brand drugs. So you can clearly see that when a company is intending to identify a product as their brand on the marketplace, they give it a specific proprietary name. They don't call it under the generic chemical compound name as every other generic has on this list. They don't give it an AWP that's below the brand AWP? I mean, everything of this product -- the AWPs, the contract prices, the generic chemical name -- was identical with the Roxane label. And guess what? Some of the DMERCs figured that out. In the first array that I gave you, DMERC A classified it as a generic the whole time. But some of them used different

procedures, and as we've seen in other instances, they were confused in terms of what they actually implemented.

But this entire classification process is unknown to a manufacturer like Roxane. What happens is, the four DMERCs construct the arrays internally. They classify things internally. We never see how they're classifying the product. Their procedures --

THE COURT: And this matters only because it says the lower of the median or the brand name?

MR. GORTNER: Exactly, your Honor. So in one scenario, what we have here is, if the product had been properly classified as a generic, you would have to do a median analysis, and putting in, as the DOJ does, the transactional prices would cause a small shift. When you allow the misclassification to stay in the brand array, that product now becomes the basis of payment for every claim of every ipratropium bromide for every quarter, irrespective of whether that happened. It never happened in the real world. Its misclassification wasn't noticed by the different DMERCs because the --

THE COURT: Okay, let me jump to the government because I now get the point.

So why is it a brand.

MR. FAUCI: The relevant regulation here, your Honor, is 42 CFR 405, 517. It's the regulation we've been

dealing with all along, which lays out reimbursement at the lower of the median or the brand. Importantly, that was adopted by CMS with several clarifications published in the Federal Register. Those say, quote, "A brand product is defined as a product that is marketed under a label name that is other than the generic chemical name of the drug or biological. CMS also made clear that it deliberately chose an expansive definition and that it specifically considered and rejected more narrow definitions." CMS noted again in the Federal Register, "If a manufacturer chooses to market its product under a proprietary name rather than the generic chemical name of the drug, we believe this is a brand. We do not limit the definition of brand to the innovator company product."

Roxane's argument depends on the idea that there's no difference between ipratropium bromide --

THE COURT: What if it has both names?

MR. FAUCI: We looked -- I think that the language covers that. If --

THE COURT: What if it's called a generic, and then it's got the tag of a brand? That's hard. That's what we're talking about here? They say it's "Ipratropium Bromide NovaPlus," so it's got both, the brand and -- I know you're emphasizing the "NovaPlus," and they're emphasizing the "Ipratropium Bromide." It's got all of them in the

title.

MR. FAUCI: Well, I mean, if you look at the language, it says, "If a manufacturer chooses to market its product under a proprietary name." There's no doubt that NovaPlus is a proprietary name. It's trademarked. It's owned by Novation. Roxane entered into an agreement with Novation to get the benefit of it.

THE COURT: What if they market under both names?

MR. FAUCI: Well, I would say that CMS specifically adopted this definition. There's other language in the Federal Register where CMS says that "We believe that it is an unreasonable burden to require our contractors to determine which of the thousands of AWPs they must look up to determine which of those are innovator drugs."

It seems clear that CMS knows that the DMERCs have a lot of things to do, and they set up a very expansive definition, so that when you look, if you look at Page 2 of the exhibit Mr. Gortner handed you, what the DMERCs did --

THE COURT: Can I say, at the very least, let's suppose you're right on the mark in terms of the regulation, but there's some ambiguity, does that make me have to go to trial on the "knowingly"?

MR. FAUCI: Absolutely. We didn't move for summary judgment on this.

THE COURT: Oh, all right. So why isn't -- all right, all right.

The ball is back in your court. So you're marketing under two sets of names, generic and brand name. It's not clear what the reg does or doesn't say, and so why did your company pick a brand name?

MR. GORTNER: Well, a couple responses. We don't agree that it's a brand name. Novation, which is what NovaPlus is referring to, has a product line of 300 generic drugs. Roxane didn't pick anything.

THE COURT: So Novation picked it.

MR. GORTNER: Novation picks it, and there are 300 generic drugs which are known in the industry as generic drugs that have a NovaPlus label because they are Novation drugs. So Roxane didn't pick anything here, step one.

Step two -- and this is on Slide 3 of what he's referring to -- this is not a regulatory definition. This is a back-and-forth and a response and comment in the Federal Register. There isn't a shred of evidence --

THE COURT: It's not an actual regulation he read me?

MR. GORTNER: It's not a regulation. What happened is --

THE COURT: Ah, it wasn't a regulation.

MR. GORTNER: Yes. If you look at Slide No. 3 --

THE COURT: I'm looking forward to these briefs. I'm sort of seeing it in realtime right now.

(Laughter.)

MR. GORTNER: Let me finish my thought. It's not a regulation. It is a response and comment back and forth. There's not a shred of evidence that Roxane knew about it, nor that that could be imputed to Roxane.

And the other issue here, your Honor, is the falsity. What we're claimed to have done isn't a naming of a drug. Causation analysis is, what's the falsity? It's reporting an AWP. If there's a second intervening step where the DMERCs get together, and whatever criteria they use or whatever they do internally, if we don't know about that, we can't know about it. Even if there's ambiguity, we win. Under the False Claims Act, when there's ambiguity, you cannot impose --

THE COURT: It strikes me that I'm going to trial on this, or is it me or Florida?

MS. ST. PETER-GRIFFITH: You.

MR. GORTNER: It's you, your Honor.

THE COURT: The happiest moment I saw was when you referred to the Southern District of Florida.

(Laughter.)

MR. DALY: That's Abbott, your Honor.

MR. GORTNER: But I reemphasize, your Honor, again

that this -- your Honor raised a pointed question, which is that what the statement says, if you choose to market under a proprietary name rather than the generic chemical name. I mean, here the reading of this particular regulation --

THE COURT: You're saying you didn't market under this name; Novation picked it.

MR. GORTNER: No. And it was also constructively erasing the generic name from the title.

MR. FAUCI: A few points, your Honor.

THE COURT: Well, what happens if Novation picks it?

MR. FAUCI: Novation operates a private-label line called the NovaPlus line. It's a trademark.

THE COURT: So Novation is marketing it.

MR. FAUCI: Roxane chose to avail itself of this. It entered agreement --

THE COURT: Everybody uses a GPO. I have a big antitrust case starting in the beginning of November involving Novation. Everybody uses GPOs.

MR. FAUCI: Well, and, quite frankly, your Honor, I mean, if you look at this list, all the other generic drugs are called "ipratropium bromide." This is the only one that has --

THE COURT: So if Novation put it on, I don't know, I mean, this is the trial issue. But I'm just

thinking that maybe this was somewhat of a little area of gray here.

MR. FAUCI: We agree it's gray, and can I just make two quick points? Novation advertises NovaPlus as a brand name. Their literature claims that NovaPlus delivers value to suppliers through, quote, "sold brand recognition," and that the, quote, "NovaPlus brand helps smaller manufacturers compete against larger manufacturers."

THE COURT: Like CVS markets under a CVS brand, so would that -- I mean, I --

MR. FAUCI: If it was included in the product name, then we say "yes." But what you don't see is that when the product is listed as the product name, it's not called "Acetaminophen CVS." It's called "Acetaminophen." Here the product is called "Ipratropium Bromide NovaPlus."

MR. GORTNER: Your Honor, with the CVS --

THE COURT: All right, I've got the debate. I understand it now, and I think it's very worth doing.

Now, I think what we need to do is, I need to turn to the government and say, how could I possibly grant summary judgment on this affirmative defense?

MR. HENDERSON: Well, your Honor, and I'll focus on Medicaid. That's where the big issue is, I think, your Honor.

THE COURT: I couldn't possibly. It's too much.

I have to work through a record.

MR. HENDERSON: And let me offer this for what it's worth, your Honor. I think the government's view is that it's the correct approach. First of all, expectations, your Honor, government expectations, irrelevant for purposes of 93A. They're not relevant to falsity under the False Claims Act. Under the False Claims Act, falsity, you look to the prevailing law; and if the Court can look at the legal standard and make a determination, then that governs the outcome of the falsity determination. And your Honor recognized this in the Mylan case.

THE COURT: I agree, but get to my question, which is at some point -- I agree with that -- at some point, if the law says you have to buy red rugs for the federal courthouse and I continue to give you blue rugs and you keep taking them, you can see they're blue, at some level, you lose a False Claims Act.

MR. HENDERSON: Well --

THE COURT: You know, that's the problem. There's a spectrum of cases, right? Some that say mere knowledge is not enough, and there's another at the other end that seems to say that you can acquiesce in something. I don't think it can be negligence, but if you actually know, you actually know year after year after year that AWP is a phony number, and you accept that because you're worried about the

pharmacies leaving the system, doesn't that support a government knowledge defense?

MR. HENDERSON: On the Medicaid side --

THE COURT: Yes, on the Medicaid.

MR. HENDERSON: No, it doesn't, your Honor, and this is why: We're not suing for the state share. We're suing for the federal share. And the federal regulations set forth a legal paradigm, a legal structure that is based on the words "estimated acquisition cost," that, as you know, the federal regulations for all time have said that the agencies shall not pay any higher than a FUL, if there is one, or the estimated acquisition cost, or the U and C.

All states, all states for at least part of the time, and all states for most of the time, have used that structure. They have reimbursed at the lower of the estimated acquisition cost or the U and C. If there's a FUL, they add that in, and, of course, if there's a MAC, they add that in. And that factual foundation for applying the federal regulatory structure is set forth in the declaration --

THE COURT: I agree with that.

MR. HENDERSON: Okay.

THE COURT: I've applied that statute more times than I can tell you. That's what's supposed to happen. That's what's supposed to happen.

MR. HENDERSON: That's right.

THE COURT: But if the government knows it's not happening, and knows it year after year after year and acquiesces, what happens?

MR. HENDERSON: And I think, obviously, if your Honor decides that the Lachman-type statements that we don't think are admissible --

THE COURT: The what kind?

MR. HENDERSON: Statements of individual state or federal officials saying, "This is what I thought, this is what I thought about the regulation," if all of that --

THE COURT: Not "what I thought about the regulation." "This is what I knew when I was approving the plan."

MR. HENDERSON: And, your Honor, the United States rests on the structure of the federal regulation. Government knowledge is not a defense to falsity. It is a defense to scienter. And when the defendants --

THE COURT: Well, that might be true.

MR. HENDERSON: Okay. And if so, if the defendants had no knowledge of all of this, and they presented no evidence that they knew about any of these government reports or relied upon them, if that's the case, then it doesn't help them. If their claims were false and it caused overpayments and they didn't know about any of

this government knowledge --

THE COURT: All right, so you're hinging the legal question, so maybe the government knew everything, but they didn't know the government knew.

MR. HENDERSON: That's correct.

THE COURT: So it's a game of double --

MR. HENDERSON: That's correct.

THE COURT: So what do you think about that, there's no evidence that you knew they knew?

MS. WITT: Your Honor, I'd turn to the -- the first example is the AMPs. At the time the government is saying, "The defendants all thought these were secret prices and didn't want the government to have them," at the same time all of these companies were sending on a quarterly basis an AMP, which is not exactly the same but which tracks what the government says the AWP should have been very, very closely.

THE COURT: "Should have" is the negligence standard. That's where I'm not willing to go --

MS. WITT: No, but our clients knew that the government had the AMPs, so the idea that they had the information from a source different than the reports, that we can't show that our clients knew about the reports but that they knew that the government had all the information they now say was secret, certainly that's exactly the same

thing.

THE COURT: Can I ask you this one last question here, which is, I started reading about relation back. Why am I doing that now? I've written so much on motion. Why is this coming up now?

MS. REID: Your Honor, I think that's in connection with the unjust enrichment.

THE COURT: No, it wasn't. They were talking about the infusion division of the most recent --

MS. ST. PETER-GRIFFITH: Your Honor --

THE COURT: -- amendments, by which it means the early 2000s, and then --

MS. ST. PETER-GRIFFITH: In that regard, Abbott has moved for summary judgment to try to exclude essentially allegations set forth in the government's Abbott amended complaint dealing with its home infusion business unit.

THE COURT: Right. So why is it coming up now whether it relates back?

MS. ST. PETER-GRIFFITH: Your Honor, we submit that it's not a proper argument, and we don't know why they brought it now. It's very straightforward, your Honor.

THE COURT: I already did the whole -- I'm not inclined to start reengaging with relation back, and I don't think it's jurisdictional. Was it triggered by the new statute? I don't understand why suddenly this briefing. I

got bogged down in it a couple nights ago, why I have to worry about relation back.

MR. HENDERSON: These are the motions to dismiss, I think, your Honor, which --

THE COURT: No, no, no. They came up again.

MR. DALY: No, the motion to dismiss is separate. We're just making a very narrow argument there, Judge, and it just relates to whether or not these allegations arise out of the same transaction or current so that they would relate back.

THE COURT: Why wasn't that made when we -- you made all these arguments way back when.

MR. DALY: I don't think we made it early on because they amended the complaint to put this in there.

THE COURT: Not till years ago they amended the complaint, right?

MS. ST. PETER-GRIFFITH: Correct, your Honor.

THE COURT: Anyway, I'm not inclined to deal with that unless I'm misunderstanding.

Then there's this new issue with the new statute and whether or not it resurrects unjust enrichment. I don't even know why I need that.

MS. REID: On that one, your Honor, if I may, I would just look at the briefing. I think that there is an adequate remedy of law under -- and I don't know --

THE COURT: I just don't think I need to decide it now.

MS. REID: No, I don't think you do need to decide it at this point.

THE COURT: You're just preserving it.

MS. REID: Well, actually, the government made the motion to have it relate back to resurrect common law claims back to the time --

THE COURT: Because there's a new statutory amendment, right?

MS. REID: Right, but the question on that is whether or not you can resurrect a common law claim, which the relator could not have brought an unjust enrichment claim in the first place --

THE COURT: And the statute again isn't clear.

MS. REID: And the statute is not clear. So I think that it's not something your Honor needs to look at because I think the end -- they're going to have to elect. I think --

THE COURT: Well, I don't know what I'm going to do, but I think if we go to trial, at some point, if I send to it Florida, I don't know what to do with it because I don't want to spend -- it isn't clear on this. It's clear that that was enacted in response to Baylor, which was an outlier case.

MS. REID: Right.

THE COURT: And it's hard unless you give me something in the legislative history to say they even thought about common law claims. You just -- on the plain language of it, it's not -- they're amending the False Claims Act.

MS. OBEREMBT: Well, Congress stated they were doing a clarifying amendment --

THE COURT: Because people went nuts over Baylor. Isn't that the name of the Judge Jacobs case? Yes, yes, people were flipping out all over the place. So unless I saw in the legislative history that it was meant to revive common law claims, I don't know why I would change my mind, but maybe it is there.

MS. OBEREMBT: I believe it is there, your Honor, and the idea is not that the claims were revived. It's that they were never lost in the first place.

THE COURT: Fine, but I want something in the legislative history to say amending the false means that relation back differs for common law claims, that Congress was even thinking about that.

MS. OBEREMBT: Well, as I said, your Honor, Congress intended a clarifying amendment stating that their earlier amendments to the False Claims Act --

THE COURT: You know what? Find it for me in the

legislative history, in the report language, in the colloquies on the floor, in the submissions from the Justice Department, something that flags for me that common law claims was part of what Congress was worried about. What everyone was worried about was that Second Circuit case. So unless somehow someone flagged to Congress the common law claims are a part of this -- has anyone here looked up the legislative history?

MS. OBEREMBT: Well, your Honor, we did brief this.

THE COURT: Yes, but you didn't give me quotes from the legislative history.

MS. OBEREMBT: Well, we'll review our briefing, and we'll file a supplemental --

THE COURT: At least, it was -- you know, as I said, I had 600 pages' worth of briefing, so can I say that it's not in one of those little footnotes I can't read? Maybe. But just I didn't notice something that explicitly said in the legislative reports or -- even the plain language isn't so plain in the context of amending the False Claims Act.

MS. REID: Your Honor, we'll both look. We looked at the legislative history and did not finding anything relating to common law. We found a lot about Baylor.

THE COURT: I bet you did. I bet you did.

But, anyway, so before we leave here today, when can we do the Daubert hearing because the damage issue on extrapolation is of concern to me. So what will I need, a morning, two mornings?

MR. LAVINE: Your Honor, I believe there's a scheduling order already in place that sets the briefing on that not to be completed until mid-November.

THE COURT: All right, so then let's get a hearing. Fair enough. Let's just get a hearing. Let's get a couple of days blocked off in the afternoon. And I like to hear from live witnesses because I never understand -- you know that quote, "Lies, damn lies, and statistics." I don't understand these statisticians until they actually show up. And what I really want is the other statistician to be sitting in the room while they're there because it limits what they can say without being too embarrassed. It's called "hot-tubbing experts," and I let the other expert ask questions. But it's got to be in plain language for me on the extrapolations because extrapolation is fully appropriate, but it's got to be with a decent methodology.

MR. LAVINE: Yes, Judge, and I think the briefing we just filed will be very helpful in giving you a better understanding of what's going on.

THE COURT: I spent a lot of time reading about it in this set of briefs, maybe too much, since no one focused

on it.

MR. LAVINE: The government's first brief was filed just yesterday.

THE COURT: All right, so what do you want, a day for each expert for direct and cross?

MR. DALY: I don't think it would take a whole day, Judge. I mean, not two days.

THE COURT: A half, a morning or an afternoon.

MR. DALY: Oh, okay. Yes, I think that would be fine, Judge.

THE COURT: So, Robert, when can we do that, like, say, early December-ish in the afternoon?

MR. LAVINE: Your Honor, our expert has a very tough schedule these days. I hesitate to --

THE COURT: Who is he?

MR. LAVINE: He's currently a senior economist for Healthcare Policy for President Obama, and he's very hard to get ahold of.

THE COURT: Who is it?

MR. LAVINE: Mark Duggan.

THE COURT: He works for the government now?

MR. LAVINE: Well, just recently he moved over to that position.

THE COURT: And he's going to be the witness? To be seen.

MR. LAVINE: Well, it's a little late to switch because of where he was, but, yes, he's --

THE COURT: Yes, he is a busy man, but I'm going to need to see him.

MR. LAVINE: No, I understand. I just wondered if there is a way we can consult his schedule as part of this process and maybe float some dates with him first.

THE COURT: Why don't I come up with a couple of dates for all of you in the room, and then if he can't make it, we'll reschedule it. So, like, sometime in early December?

Now, how long are the Daubert briefing papers because we can't have what happened on this?

MR. LAVINE: The initial motion was 30 pages, and our response was 30. I don't think there's any specific page limit set for the reply and surreply.

THE COURT: Thirty? Twenty.

MR. TORBORG: Twenty each?

THE COURT: Well, actually, what does the surreply say in the local rules?

MR. HENDERSON: Local rules don't address --

THE COURT: Why don't we leave it at ten apiece because I can't -- it really was self-defeating for all of your purposes to have so much briefing this last time around.

And now we need something on the spoliation issue. Is that evidentiary, or is it just argument?

MR. DALY: It's just argument, Judge.

THE COURT: Just argument? When do we want to do that?

MR. DALY: At the Court's convenience. That's fully briefed, so we could do that at or around the same time as --

THE COURT: Is there any other time you're going to be here so I don't bring all these folks back?

MR. DALY: I don't think we have anything else scheduled right now, your Honor, but we could do it in that time period. We also have our sort of -- each of the defendants, we have some offensive motions that we want to spend a little bit of time with the Court.

THE COURT: Spoliation isn't offensive?

MR. DALY: No, no, we have our offensive motions for summary judgment too that we've moved on and that relate to some of these damages issues.

THE COURT: I thought that's what we did today, people picked their big issues. No?

MR. TORBORG: No. Your Honor, I'm sorry, this is Dave Torborg on behalf of Abbott. We let the government start with their motions first. We haven't even touched the defendants' offensive motions. Most of the issues deal with

damage-related issues, extrapolation being one of them. Another issue is our contention that claims not paid on a reported price should be out of the case, a big issue.

THE COURT: Yes, I've read all that. That stuff I did read. I maybe spent so much time on something that wasn't -- but as I understand that, that's why I want to do -- that's what got my interest piqued for doing the Daubert hearing.

MR. DALY: Well, maybe we could do -- because they're related, Judge, it seems to me -- do it at the same time.

THE COURT: So why don't we do it at the same time.

MR. DALY: Absolutely.

THE COURT: I mean, that's what really got my interest. As you know, in another case, I'm having to deal with the FUL issue, in the New York County case maybe it is? So that actually rises to the top of my plate, and maybe I'll have a ruling by then. So, ideally speaking, we'll dovetail those? That's fine, because those were the primary issues.

MR. DALY: Yes.

THE COURT: And that's where I got the relation-back issue. So maybe I just read everything in a different order than you were planning to present, which

brings me to probably the next time around you should at least give me an agenda of what you're going to focus on so I can focus on it as well.

So we've got spoliation, we need just that date, and then I think we're home free, right?

MS. WITT: We still need a date for the B.I.P.I. and B.I.C. summary judgment, the alterego/piercing the corporate veil motion as well, which I think is probably --

THE COURT: We can do that at the same time you're all up here for the Daubert?

MS. WITT: Correct.

MS. ST. PETER-GRIFFITH: And just to briefly clarify, your Honor, the spoliation, it's not quite fully briefed. We are intending to submit a surreply on that.

THE COURT: How long?

MS. ST. PETER-GRIFFITH: Very brief, your Honor.

MS. REID: And then there is the original-source motion which is in the process. I mean, I think that's the only other pending motion.

THE COURT: Let's just get the date. We're all tired here. So when should we do the Daubert? And then it will be defendants' motions for summary judgment. Maybe two days in December, Robert, maybe mid-December?

THE CLERK: Two days back to back?

THE COURT: Well, if we can, or two afternoons

back to back. We'll see if I'm on trial. Do you have anything?

THE CLERK: We could do --

THE COURT: Are there any whole weeks that we're not on trial?

(Discussion off the record between Court and Clerk.)

THE COURT: Well, how about the 10th and the 11th in the afternoon, at least to get us going? And on the 10th and the 11th, what I'm planning on is the Daubert hearing and defendants' motions. And if I'm not on trial, we'll go full days, and if I am on trial, then we could swing over into the 21st. But I know you all want to go home, you're from different areas. What do we have on December 16? We have listed summary judgment.

MR. BREEN: I think that may be the Erie case.

THE COURT: Which one?

MR. BREEN: I was thinking about in the Abbott Erie case, your Honor, the declined Abbott case, but maybe not.

THE COURT: Well, we could do the 16th, 17th, and 18th if none of you can figure out what that is. So we'll have 16th, 17th, and 18th in the afternoon. If we needed to, we could possibly go full --

MR. DALY: Instead of the 10th and 11th, Judge?

THE COURT: Oh, I'm sorry, you're right. Why don't we do this: Why don't we do the 10th and the 11th. If I can do full days for you, I will. If I'm on trial, I can't. We have the 16th blocked off for AWP, and then if we had to, we can swing into that to come back, because we have a big agenda. We have your motions for summary judgment, we have spoliation, and we have Daubert, right?

MR. DALY: Right, Judge.

THE COURT: And you need to give me an agenda and work it out, or you should both give me your proposed agendas with what you're focusing on, and I'll set an agenda because this didn't really work so well.

MR. DALY: Judge, we also have pending, and will be fully briefed by then, our motion to dismiss on jurisdictional grounds that raises some issues relating to original source.

THE COURT: I may not do that. I can only handle so much --

MR. DALY: Just perhaps do that at another time then.

THE COURT: -- at these hearings.

MR. DALY: Okay, thanks, Judge.

THE COURT: So, now, the big issue is, last but not least, should I set a trial date? It's a jury trial. My guess is it's huge, right, a month anyway, right?

MR. HENDERSON: Considerably. I'd say it's probably more than that.

THE COURT: At least get everybody on the calendar because I think something is going to go in this court, and this is getting to be an older case. So, Robert, when could we get it? And I have so many other cases. I just set Mylan for trial. I've got the Neurontin cases, and I just need to get you on my page. Do you want to do it in May?

MS. REID: Your Honor, there is an issue, in that the government has just moved to consolidate Roxane and Dey for trial, and we need to brief that.

THE COURT: Down there.

MS. REID: No. Abbott's the one.

MR. DALY: Abbott is the one that's in Florida, Judge.

MS. REID: We're here. Maybe they'll move us to Florida. And we, of course, both strongly oppose that motion, so we would need to brief that and --

THE COURT: To what, to transfer --

MS. REID: No, to consolidate us for trial. We want separate trials. So, I mean, they've just filed the motion. We need to oppose it.

THE COURT: Let's just get something on the calendar, get something. Robert, when can we do it?

MS. REID: I mean, but we don't know which

defendant or both defendants.

THE COURT: No, we don't, but if I wait until that's all done, then I -- I'm at the mercy of the First Circuit in terms of getting new law clerks, and I have a law clerk who understands this case perfectly, and I want it done before he leaves, before I start having to train somebody completely different. So that's my concern. So we need to do it before the clerkship year ends.

MR. HENDERSON: I was just going to say, I would suggest moving it up maybe one month to May, just for preparation.

THE COURT: Maybe, maybe. When is school vacation week? Maybe right after school vacation week? Robert, do you have that date?

THE CLERK: Yes. We can do April 26.

THE COURT: Now, that's going to be jumpy a little bit. There's a First Circuit Judicial Conference I have to go to, and there's something in Washington I need to go to, but at least if we get it on the calendar, we can work around that. And he'll issue a pretrial order. And my guess is, I will try Dey and Roxane together. I haven't heard your briefs. I don't know about Abbott, whether that's just so different it would be confusing to a jury.

MR. DALY: Judge, remember, we are not in front of you for trial.

THE COURT: I understand.

MS. ST. PETER-GRIFFITH: But, your Honor, it's our objective to try and move it up here.

THE COURT: But let me just say, that may be, but at some level I've got to make simplicity for a jury, and it gets to be too much. At least those are similar drugs, right?

MS. ST. PETER-GRIFFITH: Correct, your Honor. We're not necessarily advocating at this point in time consolidating all of them, but your Honor is going to be familiar with the experts which overlap in the case, the witnesses that overlap in the case, and to us it makes sense for it to be up here.

THE COURT: Maybe, okay, but --

MS. REID: Your Honor, I just -- you know, there really are strong reasons why it would be prejudicial for Roxane and Dey to be tried together. We'll lay them out for you. We'll make it brief.

THE COURT: Sure. I'm not making a definitive ruling. I'm just saying --

MS. REID: I mean, they're different drugs in our cases and they're different issues.

THE COURT: Maybe. I don't need that argument now.

MS. REID: Okay.

THE COURT: I'm just saying I need something on the calendar. Maybe it's one and not the other, maybe flip a coin. I need to resolve, I need one, because without a trial date, you're never going to think about settlement.

Okay, so now let me go off the record and discuss that, okay, because Lee has been working all afternoon here.

(Discussion off the record.)

(Adjourned, 5:09 p.m.)

C E R T I F I C A T E

UNITED STATES DISTRICT COURT)
DISTRICT OF MASSACHUSETTS) ss.
CITY OF BOSTON)

I, Lee A. Marzilli, Official Federal Court Reporter, do hereby certify that the foregoing transcript, Pages 1 through 111 inclusive, was recorded by me stenographically at the time and place aforesaid in Civil Action No. 01-12257-PBS and 06-11337-PBS, In Re: Pharmaceutical Industry Average Wholesale Price Litigation, and thereafter by me reduced to typewriting and is a true and accurate record of the proceedings.

In witness whereof I have hereunto set my hand this 26th day of October, 2009.

/s/ Lee A. Marzilli
_____
LEE A. MARZILLI, CRR
OFFICIAL FEDERAL COURT REPORTER